

Access and Affordability Resource Guide



Please see full Prescribing Information for CIBINQO™ (abrocitinib), including BOXED WARNING and Medication Guide, enclosed in pocket.

CIBINQO
(abrocitinib) tablets

eucrisa
crisaborole ointment 2%

Copay Savings Card

Pay as little as*

\$0 CIBINQO[®]
(abrocitinib) tablets

\$10 eucrisa[®]
crisaborole ointment 2%

Eligible, commercially insured patients may pay as little as
\$0 for CIBINQO or **\$10 for EUCRISA**
with the Copay Savings Card*



*Eligibility required. No membership fees. For CIBINQO, the maximum benefit per patient is \$15,000 per calendar year. For EUCRISA, individual savings limited to \$970 per tube or \$3,880 in maximum total savings per calendar year. Only for use with commercial insurance. If you are enrolled in a state or federally funded prescription insurance program, you may not use the copay card. Terms and conditions apply (see page 9).



For CIBINQO: Interim Care Rx

If a delay or coverage denial occurs during the prior authorization or appeals process, eligible, commercially insured patients enrolled in Pfizer Dermatology Patient Access[™] may receive CIBINQO for up to 2 years at no cost shipped to them through Interim Care Rx.[†]

[†]The free product for this program is for certain commercially insured patients only. Not available to residents in the states of MA, MI, MN, MO, OH, or RI. See terms and conditions on page 10.

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4 ways patients can receive the Copay Savings Card



Patients can enroll in the Mobile Savings Program[†] to have the copay card sent to their mobile device.

- **Text** COPAY2 to 82000
- **Visit** CIBINQO.com or EUCRISA.com



Patients can receive a Copay Savings Card from you.

- **Download** a Copay Savings Card at CIBINQOHCP.com/copay, EUCRISAHCP.com/savings-and-support, or from the HCP Portal (see page 5)
- **Give your patients** the Copay Savings Card brochure or the CIBINQO Welcome Kit



Patients can download their Copay Savings Card online at CIBINQO.com or EUCRISA.com. May be downloaded as a PDF or saved to a digital wallet.



Patients can call 1-833-956-DERM (1-833-956-3376) to request a Copay Savings Card.



Request Copay Savings Cards for your patients
from your Dermatology Account Representative.

[†]See terms and conditions for mobile messaging on page 10 and Pfizer's Privacy Policy at Pfizer.com/privacy. Up to 10 messages/month. Message and data rates may apply. Text HELP to 82000 for information and STOP to opt out.

Support Services

PFIZER DERMATOLOGY
patient access

Personalized resources and support for your patients



Coverage assistance

With benefits investigation, prior authorization, and the appeals process



Pharmacy coordination

Based on your patient's preferred pharmacy



Financial assistance resources

For eligible patients*



Additional resources for patients

You and your patients can connect with a Patient Support Representative

*Some offerings are provided through third-party organizations that operate independently and are not controlled by Pfizer. Availability of offerings and eligibility requirements are determined solely by these organizations.

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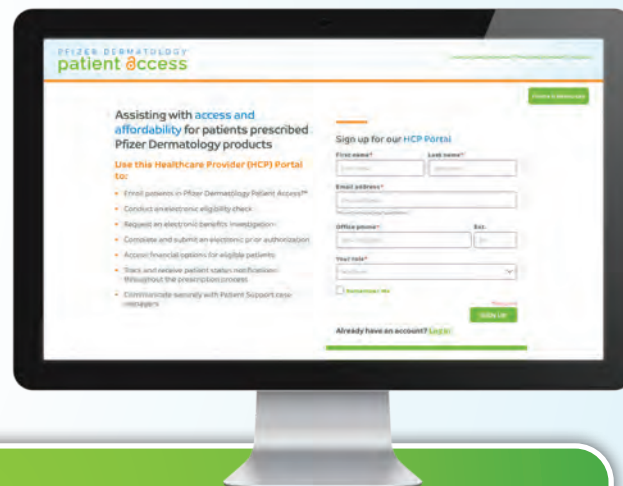
HCP Portal

Register at **PfizerDermatologyHCPPortal.com** to access resources and support for your patients online.



Your office can use it to:

- Enroll patients
- e-Prescribe and coordinate with the patient's pharmacy
- Request an electronic benefits investigation
- Complete and submit an electronic prior authorization
- Access financial options for eligible patients*
- Track and receive patient status notifications throughout the prescription process
- Download program forms and resources



The HCP Portal also allows your office to **communicate securely with a Patient Support Representative.**

Connect Your Patients to Resources and Support

1 ENROLL

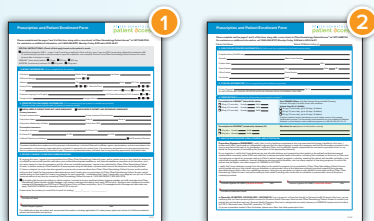
4 options to enroll your patients today

EHR: Electronically complete and submit the enrollment form*

e-Prescribe: Send prescription directly to Sonexus Health Pharmacy Services† NCPDP: 5910206; NPI: 1447680210

HCP Portal: Log in or register at PfizerDermatologyHCPPortal.com

Fax: Complete and fax pages 1 and 2 of the Prescription and Patient Enrollment Form, along with a fax cover sheet, to 1-877-548-1734

The image shows two sample pages of the Patient Enrollment Form. Page 1 (labeled with a circled '1') contains patient information fields and checkboxes for consent. Page 2 (labeled with a circled '2') contains additional patient information and checkboxes for consent.

*A link to enroll patients appears in the EHR during the e-Prescribing process. How you are directed to the form is controlled by, and varies based on, your EHR channel partner.

†If you choose to e-Prescribe directly to Sonexus Health Pharmacy Services, you are certifying that you have received patient consent for Sonexus Health Pharmacy Services and Pfizer Dermatology Patient Access to contact your patient and provide them services. Sonexus Health Pharmacy Services is categorized as a mail-order pharmacy in EMR/EHR systems and is located at 2730 S. Edmonds Lane, Suite 400, Lewisville, TX 75067.

‡See page 5 for more details on the HCP Portal.

2 GET CONSENT

Obtain patient consent for certain services

HCP Portal:

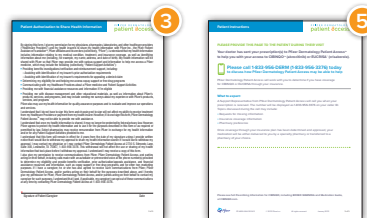
- A link can be sent by email to allow patients to opt in and sign the forms online

Patient Portal:

- Patients can register and log in to sign consent forms electronically

Print:

- Patients can sign page 3 of the Prescription and Patient Enrollment Form
- Provide page 5 of the Enrollment Form to patients. It gives patients an overview of what to expect from Pfizer Dermatology Patient Access™

The image shows two sample pages of the Patient Enrollment Form. Page 3 (labeled with a circled '3') contains patient information and checkboxes for consent. Page 5 (labeled with a circled '5') contains additional patient information and checkboxes for consent.

Request printable consent forms from Pfizer Dermatology Patient Access by calling 1-844-496-8707.

3 TRACK

Track your patients' prescription status

HCP Portal:

- If you've registered to use the HCP Portal, you can check a patient's case status online[§]

Email:

- Contact the Case Inquiry Team via email at CITE-PDPA@cardinalhealth.com. NOTE: Emails or secured messages from your office will be answered within 2 business hours[§]

Patient Portal:

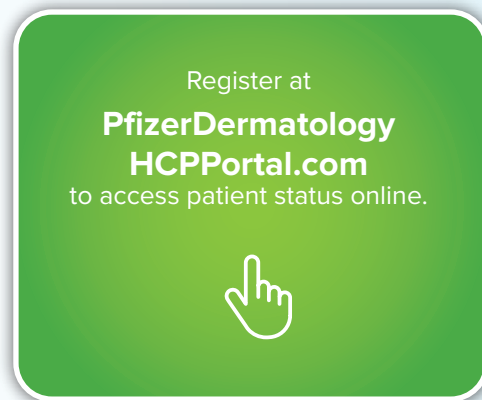
- Direct your patients to PfizerDermatologyPatientPortal.com so they can sign consent forms electronically and check their prescription status

Phone:

- Speak directly with a case manager by calling 1-844-496-8707 (available Monday-Friday, 8:00 AM-8:00 PM ET)

In Person:

- Contact your Field Reimbursement Manager (FRM) for an in-person discussion. FRMs can assist with patient-related or portal-related inquiries



[§]Email messages received after 8:00 PM ET will be returned by 10:00 AM ET the following business day.

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Prescription and Patient Enrollment Form Reminders

A If your patient has a preferred pharmacy, please enter it here.

B Remember to have the patient sign the form or provide their email address if they prefer to provide consent online. Patient consent is required for certain services.

C Remember to include the primary diagnosis and ICD-10 code.*

D If you choose to e-Prescribe directly to Sonexus Health Pharmacy Services, you are certifying that you have received patient consent for Sonexus Health Pharmacy Services and Pfizer Dermatology Patient Access™ to contact your patient and provide them services.

Prescription and Patient Enrollment Form **PFIZER DERMATOLOGY patient access**

Please complete and fax pages 1 and 2 of this form, along with a cover sheet, to Pfizer Dermatology Patient Access™ at 1-877-548-1734. For assistance or additional information, call 1-844-496-8707, Monday-Friday, 8:00 AM to 8:00 PM ET.

SPECIAL INSTRUCTIONS—Check all that apply based on the patient's needs.
☐ Benefits Investigation ONLY—pages 1 and 2 must be completed on their entirety, even if you are ONLY requesting a Benefits Investigation (BI). To avoid having to provide a new prescription upon BI completion, also complete Section 5 and Pfizer Dermatology Patient Access can move forward after a decision is made.
 CIBINQO™ (abrocitinib) tablets ☐ 50 mg ☐ 100 mg ☐ 200 mg
 EUCRISA® (isotretinoin) ointment, 2% ☐ 60-g tube ☐ 100-g tube

1. PATIENT INFORMATION (To be completed by the patient)
 First Name _____ Middle Name _____ Last Name _____
 DOB (mm/dd/yyyy) _____ Gender ☐ M ☐ F
 Address _____ City _____ State _____ ZIP _____
 Primary Phone _____ ☐ Home ☐ Alternate Phone _____ Work _____ Cell _____
 E-mail _____ Best time to reach me ☐ Morning ☐ Afternoon ☐ Evening
 Preferred Language (if not English) _____ U.S./Puerto Rico/Guam/U.S.V.I. Resident ☐ Yes ☐ No
 Caregiver Name _____ Caregiver Phone _____ ☐ H ☐ M

2. PRESCRIPTION INSURANCE INFORMATION (To be completed by the patient or healthcare provider)
☐ CHECK HERE IF PATIENT DOES NOT HAVE INSURANCE ☐ CHECK HERE IF PATIENT HAS SECONDARY INSURANCE
 Primary Insurance Name _____ Primary Insurance Phone Number _____
 Policyholder Name _____ Policy # _____ Group # _____
 Policyholder Relationship to Patient _____ Policyholder DOB _____
 Prescription Insurance _____
 Prescription Insurance _____ Rx Policy ID # _____
 Preferred Pharmacy and Address _____ ☐ Self-Dispensing Pharmacy

The patient/identified above permits use of the pharmacy indicated above. I authorize Pfizer and its affiliates, agents, representatives, and service providers to use this prescription to the pharmacy designated above, provided it is approved by the patient's physician. If the pharmacy designated is not a plan-approved pharmacy, then a pharmacy approved by the patient's physician. If there is no preferred pharmacy indicated, then to any pharmacy approved by the patient's physician.

3. PATIENT CONSENT TO RECEIVE COMMUNICATIONS
 By signing this form, I agree to communications from Pfizer, Pfizer Dermatology Patient Access, and/or parties acting on their behalf to determine my eligibility and provide benefits verification, prior authorization/appeals assistance, and financial assistance resources and information, such as copay support or free drug programs, and for other non-marketing purposes. I agree to be contacted by Pfizer, Pfizer Dermatology Patient Access, or parties working on their behalf for these purposes using an autodialer or pre-recorded voice at the telephone number(s) provided.
 If I have a caregiver, he or she has also agreed to receive such communications from Pfizer, Pfizer Dermatology Patient Access, and/or parties acting on their behalf for the purposes described above, and I hereby give my permission for Pfizer, Pfizer Dermatology Patient Access, and/or parties acting on their behalf to contact my caregiver for such purposes. I understand that I (and, if applicable, my caregiver) can opt out of these communications at any time by contacting Pfizer Dermatology Patient Access at 1-833-956-DEIRM (1-833-956-3376).
☐ By checking this box and providing my cellular number, I consent to receive electronic alerts, shipping updates, and e-mail newsletters from Pfizer Dermatology Patient Access via text message. I will receive a welcome text asking me to reply YES to opt in. See terms and conditions for mobile messaging at Engage.com/PSMA and Pfizer's Privacy Policy at Pfizer.com/privacy. Up to 10 messages/month. Message and data rates may apply. Text HELP to 80000 for information and STOP to opt out.
 Please enter the number you would like to enroll for texting: () _____

4. SIGNATURES
☐ Print Name of Patient _____
☐ Print Caregiver Signature _____ Date _____

For details about how we collect and use personal information, including applicable U.S. state privacy rights and notices for California residents, please visit www.pfizer.com/privacy.

PAGE 1

Prescription and Patient Enrollment Form **PFIZER DERMATOLOGY patient access**

Please complete and fax pages 1 and 2 of this form, along with a cover sheet, to Pfizer Dermatology Patient Access™ at 1-877-548-1734. For assistance or additional information, call 1-844-496-8707, Monday-Friday, 8:00 AM to 8:00 PM ET.

Patient Full Name _____ Patient DOB (mm/dd/yyyy) _____

4. HEALTHCARE PROVIDER INFORMATION (All fields must be completed by the healthcare provider)
 Prescriber Name (First/Last) _____
 Specialty _____ State License Number _____
 Practice Name _____ NPI# _____
 Street Address _____ City _____ State _____ ZIP _____
 Office Contact _____ Phone Number _____
 Fax Number _____ Email _____

5. CLINICAL INFORMATION (To be completed by the healthcare provider)
 Primary Diagnosis _____ ICD-10 _____
DO NOT ATTACH ANY CLINICAL OR OFFICE NOTES AS THIS MAY DELAY PROCESSING THE FORM.

6. PRESCRIPTION INFORMATION (To be completed by the healthcare provider)
☐ 50 mg PO once daily Quantity _____ Refills _____
☐ 100 mg PO once daily Quantity _____ Refills _____
☐ 200 mg PO once daily Quantity _____ Refills _____
☐ 60-g tube Quantity _____ Refills _____
☐ 100-g tube Quantity _____ Refills _____

7. HEALTHCARE PROVIDER HIPAA CONSENT AND ATTESTATION
Prescriber Signature (REQUIRED) I certify that I am the healthcare professional who has prescribed the therapy identified in this form. I further certify that I have made an independent judgment that the above therapy is medically necessary and that the information provided in this form is accurate to the best of my knowledge. I authorize Pfizer and its affiliates, agents, representatives, and service providers to act on my behalf for the purpose of transmitting this prescription to the appropriate pharmacy.
 By my signature, I certify that I have obtained any and all authorizations and consents from the patient or the patient's authorized personal representative necessary under HIPAA and state law to release protected health information, including that contained on this form, to Pfizer and its employees or agents for purposes relating to Pfizer's patient support programs, including, assisting the patient with benefits verification, prior authorization/appeals assistance, financial assistance resources and information, such as copay support or free drug programs, for which the patient may be eligible, and other support for CIBINQO or EUCRISA.
 I certify that I have obtained consent from the patient or the patient's caregiver to be contacted by Pfizer Dermatology Patient Access, and/or parties acting on their behalf using an autodialer or pre-recorded voice at the telephone number(s) provided regarding the purposes described above, and I hereby give my permission for Pfizer, Pfizer Dermatology Patient Access, and/or parties acting on their behalf to contact my caregiver for such purposes. I understand that I (and, if applicable, my caregiver) can opt out of these communications at any time by contacting Pfizer Dermatology Patient Access at 1-833-956-DEIRM (1-833-956-3376).
☐ Prescriber Signature NO STAMPS (Signature as Witness) _____ Date _____
☐ Prescriber Signature NO STAMPS (Signature as Witness) _____ Date _____
 Print Name of Healthcare Provider _____

8. E-PRESCRIBE ID (REQUIRED) 5910206, NPI: 1447680210. If you choose to e-Prescribe directly to Sonexus Health Pharmacy Services, you are certifying that you have received patient consent for Sonexus Health Pharmacy Services and Pfizer Dermatology Patient Access to contact your patient and provide them services. Sonexus Health Pharmacy Services is categorized as a retail pharmacy in EMV/EHR systems and is located at 2705 S. Edwards Lane, Suite 300, Lewisville, TX 75057.
 If you are a prescriber based in New York state, please use a New York state prescription form.

PAGE 2

*For additional information, go to the Centers for Medicare and Medicaid Services website at www.cms.gov or consult with your practice administrator.

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Copay Savings Card: TERMS AND CONDITIONS

By using the Pfizer Dermatology Patient Access™ Copay Savings Card, you acknowledge that you currently meet the eligibility criteria and will comply with the terms and conditions described below:

- You are not eligible to use this card if you are enrolled in a state or federally funded prescription insurance program, including but not limited to Medicare, Medicaid, TRICARE, Veterans Affairs health care, a state prescription drug assistance program, or the Government Health Insurance Plan available in Puerto Rico (formerly known as “La Reforma de Salud”).
- You must have commercial insurance. Offer is not valid for cash-paying patients.
- By using this copay card at participating pharmacies, eligible patients with commercial prescription drug insurance coverage for CIBINQO™ (abrocitinib) may pay as little as \$0 per month. Eligible patients with commercial prescription drug coverage may receive a maximum benefit of \$15,000 per calendar year, which is defined by the date of enrollment through December 31st of the enrollment year. After a maximum of \$15,000, you will be responsible for paying the remaining monthly out-of-pocket costs.
- By using this copay card at participating pharmacies, eligible patients with commercial prescription drug insurance coverage for EUCRISA® (crisaborole) may pay as little as \$10 per tube. Eligible patients with commercial prescription drug insurance coverage that **does not** cover EUCRISA may pay as little as \$100 per tube. Individual savings are limited to \$970 per tube. Individual patient savings are limited to \$3,880 in maximum total savings per calendar year.
- This copay card is not valid when the entire cost of your prescription drug is eligible to be reimbursed by your commercial insurance plan or any other health or pharmacy benefit program.
- You must deduct the value of this copay card from any reimbursement request submitted to your commercial insurance plan, either directly by you or on your behalf.

- You are responsible for reporting use of the copay card to any commercial insurer, health plan, or other third party that pays for or reimburses any part of the prescription filled using the copay card, as may be required. You should not use the copay card if your insurer or health plan prohibits use of manufacturer copay cards.
- Eligible, commercially insured patients prescribed CIBINQO must be 18 years of age or older to redeem the card.
- This copay card is not valid where prohibited by law.
- Copay card cannot be combined with any other savings, free trial, or similar offer for the specified prescription.
- **Copay card will be accepted only at participating pharmacies.**
- **If your pharmacy does not participate, you may be able to submit a request for a rebate in connection with this offer.**
- **This copay card is not health insurance.**
- Offer good only in the United States and Puerto Rico.
- Copay card is limited to 1 per person during this offering period and is not transferable.
- A copay card may not be redeemed more than once per 30 days per patient.
- No other purchase is necessary.
- Data related to your redemption of the copay card may be collected, analyzed, and shared with Pfizer, for market research and other purposes related to assessing Pfizer's programs. Data shared with Pfizer will be aggregated and de-identified; it will be combined with data related to other copay card redemptions and will not identify you.
- Pfizer reserves the right to rescind, revoke, or amend this offer at any time without notice.
- Offer expires 12/31/2023.

For questions or additional support, call 1-833-956-3376, write to Pfizer Inc. at PO Box 29387, Mission, KS 66201, or visit the CIBINQO website at www.CIBINQO.com or the EUCRISA website at www.EUCRISA.com.

Interim Care Rx Program: TERMS AND CONDITIONS

Interim Care Rx is not health insurance and is available for eligible, commercially insured patients only. Offer is only available to patients who have been diagnosed with an FDA-approved indication for CIBINQO™ (abrocitinib). No claim for reimbursement for product dispensed pursuant to this offer may be submitted to any third-party payer. Not available to patients covered under Medicaid, Medicare or other federal or state healthcare programs, including any state prescription drug assistance programs and the Government Health Insurance Plan or for residents of Massachusetts, Michigan, Minnesota, Missouri, Ohio, or Rhode Island. Available up to a 30-day supply. Refills are subject to limitations. Interim Care Rx offer does not require, nor will be made contingent on, purchase requirements of any kind. Pfizer reserves the right to amend, rescind, or discontinue this program at any time without notification. Interim Care Rx can only be dispensed by the exclusive pharmacy and only after benefits investigation has been completed and a delay occurs in the prior authorization or appeals process. Offer good only in the U.S. and Puerto Rico. Prescription must be provided by a healthcare provider licensed in the U.S. or Puerto Rico. Continued eligibility for the program requires submission of two appeals within 180 days of enrollment. After 12 months of program enrollment, an updated prescription and benefits investigation is required to confirm continued eligibility. Additional eligibility criteria may apply. Contact Pfizer Dermatology Patient Access™ at 1-833-956-3376 for details.

Mobile Text Program: TERMS

1. By opting into the Pfizer Dermatology Patient Access mobile program ("Program"), in which you can receive your Copay Savings Card via text, you consent to receive up to 10 text messages and/or push notifications per month from Pfizer Inc. Such messages may be marketing or non-marketing messages and may include, for example,

refill reminders, fill confirmation, website information for Pfizer Dermatology Patient Access support, etc. Carriers are NOT liable for delayed or undelivered messages.

2. To stop receiving text messages, text STOP to 82000. DOING SO WILL ONLY OPT YOU OUT OF THE PFIZER DERMATOLOGY PATIENT ACCESS MOBILE PROGRAM; you will remain opted in to any other Pfizer Inc. text message program(s) to which you separately opted in. You may unsubscribe from the Mobile Wallet Message Program at any time by disabling push notifications or removing the Mobile Wallet pass from your device for Mobile Wallet programs.
3. To request more information or to obtain help, text HELP to 82000. You can also call customer service at 1-800-725-4125.
4. You represent that you are the account holder for the mobile telephone number(s) that you provide to opt in to the texting program. You are responsible for notifying Pfizer Inc. immediately if you change your mobile telephone number. You may notify Pfizer Inc. of a number change by re-enrolling in the program.
5. Message and data rates may apply to each text message sent or received in connection with the texting program, as provided in your mobile telephone service rate plan, in addition to any applicable roaming charges. Charges are both billed and payable to your mobile service provider or deducted from your prepaid account. Pfizer Inc. does not impose a separate fee for sending text messages.
6. Data obtained from you in connection with this Short Message Service (SMS) texting program may include your telephone number; your carrier's name; and the date, time, and content of your messages. Pfizer Inc. may use this information to contact you and to provide the services you request from us.

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7. You understand that data obtained from you in connection with your registration for, and use of, the Program may include, for example, your phone number, related carrier information, device information, and elements of pharmacy claim information. This data may be used to administer this program and to provide program benefits such as savings offers, information about your prescription, refill reminders, as well as program updates and alerts sent directly to your device. Please read our full corporate **Privacy Policy**, which is incorporated by reference into these Terms.
8. In addition to the data use practices described in the Privacy Policy, we may send you Offer-related push notifications when your device is in the physical proximity of your pharmacy or healthcare provider. This is done through geofencing technology, which is built in to your device. Your device's location will not be known or tracked by Pfizer Inc. or its service providers. Nonetheless, you may opt out of geofencing and receiving these notifications at any time by (1) disabling location services for your Mobile Wallet app in your device's settings, (2) disabling notifications (i.e., automatic updates) within the Mobile Wallet app, or (3) removing the eCard from your Mobile Wallet by selecting "Remove Pass" within the Mobile Wallet app.
9. Pfizer Inc. will not be liable for any delays in the receipt of any SMS messages, as delivery is subject to effective transmission from your network operator.
10. The service is available only on these US participating mobile carriers: Verizon Wireless, Sprint, Nextel, Boost Mobile, T-Mobile, AT&T, Alltel, ACS Wireless, Bluegrass Cellular, Carolina West Wireless, Cellcom, Cellular One of East Central Illinois (ECIT), Cincinnati Bell, Cricket Wireless, C Spire Wireless, Duet IP (AKA Max/Benton/Albany), Element Mobile, Epic Touch, GCI Communication, Golden State Cellular, Hawkeye (Chat Mobility), Hawkeye (NW Missouri Cellular), Illinois Valley Cellular (IVC), Inland Cellular, iWireless, Keystone Wireless (Immix/PC Management), MetroPCS, Mobi PCS, Mosaic Telecom, MTPCS/Cellular One (Cellone Nation), Nex-Tech Wireless, nTelos, Panhandle Telecommunications, Pioneer, Plateau, Revol Wireless, Rina-Custer, Rina-All West, Rina-Cambridge Telecom Coop, Rina-Eagle Valley Comm, Rina-Farmers Mutual Telephone Co, Rina-Nucla Nutria Telephone Co, Rina-Silver Star, Rina-South Central Comm, Rina-Syringa, Rina-UBET, Rina-Manti, Simmetry Wireless, South Canaan (Cellular One of NEPA), Thumb Cellular, Union Wireless, United Wireless, U.S. Cellular, Viaero Wireless, Virgin Mobile, West Central Wireless (includes Five Star Wireless).
11. You agree to indemnify Pfizer Inc. and parties texting on its behalf in full for all claims, expenses, and damages related to or caused in whole or in part by your failure to notify us if you change your telephone number, including but not limited to all claims, expenses, and damages related to or arising under the Telephone Consumer Protection Act.
12. Pfizer Inc. may suspend or terminate your receipt of text messages if it believes you are in breach of these SMS Terms and Conditions. Your receipt of text messages is also subject to termination in the event that your mobile telephone service terminates or lapses. Pfizer Inc. reserves the right to modify or discontinue, temporarily or permanently, all or any part of the text messaging services you receive, with or without notice.
13. Pfizer Inc. may revise, modify, or amend these SMS Terms and Conditions at any time. Any such revision, modification, or amendment shall take effect when it is posted to Pfizer Inc.'s website. You agree to review these SMS Terms and Conditions periodically to ensure that you are aware of any changes. Your continued consent to receive text messages will indicate your acceptance of those changes.

PFIZER DERMATOLOGY patient access

- ✓ **Savings** for eligible, commercially insured patients with the Copay Savings Card
- ✓ **Personalized support** such as coverage assistance, pharmacy coordination, and financial assistance resources
- ✓ **Access** to patient prescription status through multiple channels



HCP Portal

Register and log in at
PfizerDermatologyHCPPortal.com



Phone

Call 1-844-496-8707 to speak
live with a case manager
Monday-Friday,
8:00 AM-8:00 PM ET



Email

Contact the Case
Inquiry Team via email
at CITe-PDPA@cardinalhealth.com

Please see full Prescribing Information for CIBINQO™ (abrocitinib), including **BOXED WARNING** and Medication Guide, enclosed in pocket.



HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use CIBINQO safely and effectively. See full prescribing information for CIBINQO.

CIBINQO™ (abrocitinib) tablets, for oral use
Initial U.S. Approval: 2022

WARNING: SERIOUS INFECTIONS, MORTALITY, MALIGNANCY, MAJOR ADVERSE CARDIOVASCULAR EVENTS (MACE), and THROMBOSIS
See full prescribing information for complete boxed warning.

- Increased risk of serious bacterial, fungal, viral and opportunistic infections leading to hospitalization or death, including tuberculosis (TB). Discontinue treatment with CIBINQO if serious or opportunistic infection occurs. Test for latent TB before and during therapy; treat latent TB prior to use. Monitor all patients for active TB during treatment, even patients with initial negative latent TB test. (5.1)
- Higher rate of all-cause mortality, including sudden cardiovascular death, with another JAK inhibitor vs. TNF blockers in rheumatoid arthritis (RA) patients. CIBINQO is not approved for use in RA patients. (5.2)
- Malignancies have occurred with CIBINQO. Higher rate of lymphomas and lung cancers with another JAK inhibitor vs. TNF blockers in RA patients. (5.3)
- MACE has occurred with CIBINQO. Higher rate of MACE (defined as cardiovascular death, myocardial infarction, and stroke) with another JAK inhibitor vs. TNF blockers in RA patients. (5.4)
- Thrombosis has occurred with CIBINQO. Increased incidence of pulmonary embolism, venous and arterial thrombosis with another JAK inhibitor vs. TNF blockers. (5.5)

INDICATIONS AND USAGE

CIBINQO is a Janus kinase (JAK) inhibitor indicated for the treatment of adults with refractory, moderate-to-severe atopic dermatitis whose disease is not adequately controlled with other systemic drug products, including biologics, or when use of those therapies is inadvisable. (1)

Limitation of Use: CIBINQO is not recommended for use in combination with other JAK inhibitors, biologic immunomodulators, or with other immunosuppressants.

DOSAGE AND ADMINISTRATION

- For recommended testing, evaluations and procedures prior to CIBINQO initiation, see Full Prescribing Information. (2.1)
- Recommended dosage is 100 mg orally once daily. (2.2)
- 200 mg orally once daily is recommended for those patients who are not responding to 100 mg once daily. (2.2)
- Moderate renal impairment: 50 mg once daily or 100 mg once daily for those patients who are not responding to 50 mg once daily. (2.3)
- CYP2C19 poor metabolizer: 50 mg once daily or 100 mg once daily for those patients who are not responding to 50 mg once daily. (2.4)
- For dosage modifications for certain adverse reactions, see Full Prescribing Information. (2.6)

DOSAGE FORMS AND STRENGTHS

CIBINQO Tablets: 50 mg, 100 mg, and 200 mg (3)

CONTRAINDICATIONS

Antiplatelet therapies except for low-dose aspirin (≤ 81 mg daily), during the first 3 months of treatment. (4)

WARNINGS AND PRECAUTIONS

- **Laboratory Abnormalities:** Laboratory monitoring is recommended due to potential changes in platelets, lymphocytes, and lipids. (5.6)
- **Immunizations:** Avoid use of live vaccines prior to, during, and immediately after CIBINQO treatment. (5.7)

ADVERSE REACTIONS

Most common adverse reactions ($\geq 1\%$) in subjects receiving 100 mg and 200 mg include: nasopharyngitis, nausea, headache, herpes simplex, increased blood creatinine phosphokinase, dizziness, urinary tract infection, fatigue, acne, vomiting, oropharyngeal pain, influenza, gastroenteritis. Most common adverse reactions ($\geq 1\%$) in subjects receiving either 100 mg or 200 mg also include: impetigo, hypertension, contact dermatitis, upper abdominal pain, abdominal discomfort, herpes zoster, and thrombocytopenia. (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact Pfizer Inc. at 1-800-438-1985 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

DRUG INTERACTIONS

- Strong inhibitors of CYP2C19: The recommended dose is 50 mg daily or 100 mg once daily for those patients who are not responding to 50 mg once daily. (2.5, 7.1)
- Moderate to strong inhibitors of both CYP2C19 and CYP2C9, or strong CYP2C19 or CYP2C9 inducers: Avoid concomitant use. (7.1)
- P-gp substrate where small concentration changes may lead to serious or life-threatening toxicities: Monitor or titrate dosage of P-gp substrate. (7.2)

USE IN SPECIFIC POPULATIONS

- **Lactation:** Breastfeeding not recommended. (8.2)
- **Renal Impairment:** Avoid use in patients with severe renal impairment or end-stage renal disease. (8.6)
- **Hepatic Impairment:** Avoid use in patients with severe hepatic impairment. (8.7)

See 17 for PATIENT COUNSELING INFORMATION and Medication Guide.

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FULL PRESCRIBING INFORMATION

WARNING: SERIOUS INFECTIONS, MORTALITY, MALIGNANCY, MAJOR ADVERSE CARDIOVASCULAR EVENTS, and THROMBOSIS

Serious Infections

Patients treated with CIBINQO may be at increased risk for developing serious infections that may lead to hospitalization or death; The most frequent serious infections reported with CIBINQO were herpes simplex, herpes zoster, and pneumonia [see *Warnings and Precautions (5.1)* and *Adverse Reactions (6.1)*].

If a serious or opportunistic infection develops, discontinue CIBINQO and control the infection.

Reported infections from Janus kinase (JAK) inhibitors used to treat inflammatory conditions:

- Active tuberculosis, which may present with pulmonary or extrapulmonary disease. Test for latent TB before and during therapy; treat latent TB prior to use. Monitor all patients for active TB during treatment, even patients with initial negative, latent TB test.
- Invasive fungal infections, including cryptococcosis and pneumocystosis. Patients with invasive fungal infections may present with disseminated, rather than localized, disease.
- Bacterial, viral, including herpes zoster, and other infections due to opportunistic pathogens.

Avoid use of CIBINQO in patients with an active, serious infection including localized infections. The risks and benefits of treatment with CIBINQO should be carefully considered prior to initiating therapy in patients with chronic or recurrent infections.

Patients should be closely monitored for the development of signs and symptoms of infection during and after treatment with CIBINQO, including the possible development of tuberculosis in patients who tested negative for latent tuberculosis infection prior to initiating therapy [see *Warnings and Precautions (5.1)*].

Mortality

In a large, randomized, postmarketing safety study in rheumatoid arthritis (RA) patients 50 years of age and older with at least one cardiovascular risk factor comparing another JAK inhibitor to TNF blocker treatment, a higher rate of all-cause mortality, including sudden cardiovascular death, was observed with the JAK inhibitor. CIBINQO is not approved for use in RA patients [see *Warnings and Precautions (5.2)*].

Malignancies

Malignancies were reported in patients treated with CIBINQO. Lymphoma and other malignancies have been observed in patients receiving JAK inhibitors used to treat inflammatory conditions. In RA patients treated with another JAK inhibitor, a higher rate of malignancies (excluding non-melanoma skin cancer (NMSC)) was observed when compared with TNF blockers. Patients who are current or past smokers are at additional increased risk [see *Warnings and Precautions (5.3)*].

Major Adverse Cardiovascular Events

Major adverse cardiovascular events were reported in patients treated with CIBINQO. In RA patients 50 years of age and older with at least one cardiovascular risk factor treated with another JAK inhibitor, a higher rate of major adverse cardiovascular events (MACE) (defined as cardiovascular death, myocardial infarction, and stroke), was observed when compared with TNF blockers. Patients who are current or past smokers are at additional increased risk. Discontinue

CIBINQO in patients that have experienced a myocardial infarction or stroke [see Warnings and Precautions (5.4)].

Thrombosis

Deep venous thrombosis (DVT) and pulmonary embolism (PE) have been reported in patients treated with CIBINQO. Thrombosis, including PE, DVT, and arterial thrombosis have been reported in patients receiving JAK inhibitors used to treat inflammatory conditions. Many of these adverse reactions were serious and some resulted in death. In RA patients 50 years of age and older with at least one cardiovascular risk factor treated with another JAK inhibitor, a higher rate of thrombosis was observed when compared with TNF blockers. Avoid CIBINQO in patients at risk. If symptoms of thrombosis occur, discontinue CIBINQO and treat appropriately [see Warnings and Precautions (5.5)].

1 INDICATIONS AND USAGE

CIBINQO is indicated for the treatment of adults with refractory, moderate-to-severe atopic dermatitis whose disease is not adequately controlled with other systemic drug products, including biologics, or when use of those therapies is inadvisable.

Limitations of Use

CIBINQO is not recommended for use in combination with other JAK inhibitors, biologic immunomodulators, or with other immunosuppressants.

2 DOSAGE AND ADMINISTRATION

2.1 Recommended Testing, Evaluations, and Procedures Prior to Treatment Initiation

Perform the following tests and evaluations prior to CIBINQO initiation:

- Tuberculosis (TB) infection evaluation – CIBINQO initiation is not recommended in patients with active TB. For patients with latent TB or those with a negative latent TB test who are at high risk for TB, start preventive therapy for latent TB prior to initiation of CIBINQO [see Warnings and Precautions (5.1)].
- Viral hepatitis screening in accordance with clinical guidelines – CIBINQO initiation is not recommended in patients with active hepatitis B or hepatitis C [see Warnings and Precautions (5.1)].
- A complete blood count (CBC) – CIBINQO initiation is not recommended in patients with a platelet count $<150,000/\text{mm}^3$, an absolute lymphocyte count $<500/\text{mm}^3$, an absolute neutrophil count $<1,000/\text{mm}^3$, or a hemoglobin value $<8 \text{ g/dL}$ [see Warnings and Precautions (5.6)].

Complete any necessary immunizations, including herpes zoster vaccinations, in agreement with current immunization guidelines prior to CIBINQO initiation [see Warnings and Precautions (5.7)].

2.2 Recommended Dosage

The recommended dosage of CIBINQO is 100 mg orally once daily.

If an adequate response is not achieved with CIBINQO 100 mg orally daily after 12 weeks, consider increasing dosage to 200 mg orally once daily. Discontinue therapy if inadequate response is seen after dosage increase to 200 mg once daily.

CIBINQO can be used with or without topical corticosteroids.

If a dose is missed, administer the dose as soon as possible unless it is less than 12 hours before the next dose, in which case skip the missed dose. Thereafter, resume dosing at the regular scheduled time.

2.3 Recommended Dosage in Patients with Renal Impairment or Hepatic Impairment

Renal Impairment

CIBINQO dosage recommendations for patients with renal impairment are provided in Table 1 [see *Use in Specific Populations* (8.6) and *Clinical Pharmacology* (12.3)]. In subjects with mild and moderate renal impairment, if an adequate response is not achieved after 12 weeks, dose of CIBINQO can be doubled [see *Dosage and Administration* (2.2)].

Table 1. Dosage Recommendations in Patients with Renal Impairment

Renal Impairment Stage	Estimated Glomerular Filtration (eGFR) ¹	Dosage
Mild	60 – 89 mL/minute	CIBINQO 100 mg once daily
Moderate	30 – 59 mL/minute	CIBINQO 50 mg once daily
Severe ²	15 – 29 mL/minute	Not recommended for use
End-Stage Renal Disease ² (ESRD)	<15 mL/minute	

¹ Glomerular filtration rate was estimated by the Modification of Diet in Renal Disease (MDRD) formula.

² Severe Renal Impairment and End-Stage Renal Disease include patients on renal replacement therapy.

Hepatic Impairment

CIBINQO is not recommended for use in patients with severe hepatic impairment [see *Use in Specific Populations* (8.7) and *Clinical Pharmacology* (12.3)].

2.4 Recommended Dosage in CYP2C19 Poor Metabolizers

In patients who are known or suspected to be CYP2C19 poor metabolizers, the recommended dosage of CIBINQO is 50 mg once daily [see *Use in Specific Populations* (8.8) and *Clinical Pharmacology* (12.5)]. If an adequate response is not achieved with CIBINQO 50 mg orally daily after 12 weeks, consider increasing dosage to 100 mg orally once daily. Discontinue therapy if inadequate response is seen after dosage increase to 100 mg once daily.

2.5 Dosage Modifications due to Strong Inhibitors

In patients taking strong inhibitors of cytochrome P450 (CYP) 2C19 reduce the dosage to 50 mg once daily [see *Drug Interactions* (7.1) and *Clinical Pharmacology* (12.3)]. If an adequate response is not achieved with CIBINQO 50 mg orally daily after 12 weeks, consider increasing dosage to 100 mg orally once daily. Discontinue therapy if inadequate response is seen after dosage increase to 100 mg once daily.

2.6 Treatment Discontinuation due to Serious Infections or Hematologic Adverse Reactions

Serious or Opportunistic Infections

If a patient develops a serious or opportunistic infection, discontinue CIBINQO and control the infection. The risks and benefits of treatment with CIBINQO should be carefully considered prior to reinitiating therapy with CIBINQO [see *Warnings and Precautions* (5.1)].

Hematologic Abnormalities

Recommendations for CIBINQO discontinuation for laboratory abnormalities are summarized in Table 2.

Table 2. Recommendations for CIBINQO Discontinuation for Hematologic Abnormalities

Laboratory Measure	Recommendation
Platelet Count <50,000/mm ³	Discontinue CIBINQO and follow with CBC until >100,000/mm ³
ALC <500/mm ³	Treatment should be temporarily discontinued if ALC is less than 500 cells/mm ³ and may be restarted once ALC return above this value
ANC <1,000/mm ³	Treatment should be temporarily discontinued if ANC is less than 1,000 cells/mm ³ and may be restarted once ANC return above this value
Hb value <8 g/dL	Treatment should be temporarily discontinued if Hb is less than 8 g/dL and may be restarted once Hb return above this value

Abbreviations: ALC=absolute lymphocyte count; ANC=absolute neutrophil count; CBC=complete blood count; Hb=hemoglobin

CBC evaluations are recommended at baseline, 4 weeks after treatment initiation and 4 weeks after dosing increase of CIBINQO. Laboratory evaluations may be extended for patients on chronic CIBINQO therapy who develop hematologic abnormalities [see *Warnings and Precautions* (5.6)].

2.7 Administration Instructions

Administer CIBINQO with or without food at approximately the same time each day.

Swallow CIBINQO tablets whole with water. Do not crush, split, or chew CIBINQO tablets.

3 DOSAGE FORMS AND STRENGTHS

- 50 mg: Pink, oval, film-coated tablet debossed with “PFE” on one side and “ABR 50” on the other.
- 100 mg: Pink, round, film-coated tablet debossed with “PFE” on one side and “ABR 100” on the other.
- 200 mg: Pink, oval, film-coated tablet debossed with “PFE” on one side and “ABR 200” on the other.

4 CONTRAINDICATIONS

CIBINQO is contraindicated in patients taking antiplatelet therapies, except for low-dose aspirin (≤ 81 mg daily), during the first 3 months of treatment [see *Warnings and Precautions* (5.6), *Drug Interactions* (7.2), and *Clinical Pharmacology* (12.2)].

5 WARNINGS AND PRECAUTIONS

5.1 Serious Infections

The most frequent serious infections reported in clinical studies with CIBINQO for atopic dermatitis were herpes simplex, herpes zoster, and pneumonia [see *Adverse Reactions* (6.1)]. Serious infections leading to hospitalization or death, including tuberculosis and bacterial, invasive fungal, viral, and other opportunistic infections, have occurred in patients receiving JAK inhibitors used to treat inflammatory conditions.

Avoid use of CIBINQO in patients with active, serious infection including localized infections.

Consider the risks and benefits of treatment prior to initiating CIBINQO in patients:

- with chronic or recurrent infection
- who have been exposed to tuberculosis

- with a history of a serious or an opportunistic infection
- who have resided or traveled in areas of endemic tuberculosis or endemic mycoses
- with underlying conditions that may predispose them to infection

Closely monitor patients for the development of signs and symptoms of infection during and after treatment with CIBINQO. If a patient develops a serious or opportunistic infection, discontinue CIBINQO. Initiate complete diagnostic testing and appropriate antimicrobial therapy. The risks and benefits of treatment with CIBINQO should be carefully considered prior to reinitiating therapy with CIBINQO.

Tuberculosis

Evaluate and test patients for TB before starting CIBINQO therapy and consider yearly screening for patients in highly endemic areas for TB. CIBINQO is not recommended for use in patients with active TB. For patients with a new diagnosis of latent TB or prior untreated latent TB, or for patients with a negative test for latent TB but who are at high risk for TB infection, start preventive therapy for latent TB prior to initiation of CIBINQO. Monitor patients for the development of signs and symptoms of TB, including patients who were tested negative for latent TB infection prior to initiating therapy.

Viral Reactivation

Viral reactivation, including herpes virus reactivation (e.g., herpes zoster, herpes simplex), was reported in clinical studies with CIBINQO [see *Adverse Reactions* (6.1)]. If a patient develops herpes zoster, consider interrupting CIBINQO until the episode resolves.

Hepatitis B virus (HBV) reactivation has been reported in patients receiving JAK inhibitors. Perform viral hepatitis screening and monitoring for reactivation in accordance with clinical guidelines before starting therapy and during therapy with CIBINQO. CIBINQO is not recommended for use in patients with active hepatitis B or hepatitis C [see *Clinical Pharmacology* (12.3)]. Monitor patients with inactive HBV for expression of HBV DNA during therapy with CIBINQO. If HBV DNA is detected during therapy with CIBINQO, consult a liver specialist.

5.2 Mortality

In a large, randomized, postmarketing safety study of another JAK inhibitor in rheumatoid arthritis (RA) patients 50 years of age and older with at least one cardiovascular risk factor, a higher rate of all-cause mortality, including sudden cardiovascular death, was observed in patients treated with the JAK inhibitor compared with TNF blockers. CIBINQO is not approved for use in RA.

Consider the benefits and risks for the individual patient prior to initiating or continuing therapy with CIBINQO.

5.3 Malignancy and Lymphoproliferative Disorders

Malignancies, including non-melanoma skin cancer (NMSC), were observed in clinical studies with CIBINQO for atopic dermatitis [see *Adverse Reactions* (6.1)].

Perform periodic skin examination for patients who are at increased risk for skin cancer. Exposure to sunlight and UV light should be limited by wearing protective clothing and using broad-spectrum sunscreen.

Malignancies, including lymphomas, have occurred in patients receiving JAK inhibitors used to treat inflammatory conditions. In a large, randomized, postmarketing safety study of another JAK inhibitor in RA patients, a higher rate of malignancies (excluding non-melanoma skin cancer (NMSC)) was observed in patients treated with the JAK inhibitor compared to those treated with TNF blockers. CIBINQO is not approved for use in RA. A higher rate of lymphomas was observed in patients treated with the JAK inhibitor compared to those treated with TNF blockers. A higher rate of lung cancers was observed in current or past smokers treated with the JAK inhibitor compared to those treated with TNF blockers. In this study, current or past smokers had an additional increased risk of overall malignancies.

Consider the benefits and risks for the individual patient prior to initiating or continuing therapy with CIBINQO, particularly in patients with a known malignancy (other than a successfully treated NMSC), patients who develop a malignancy when on treatment, and patients who are current or past smokers.

5.4 Major Adverse Cardiovascular Events

Major adverse cardiovascular events were reported in clinical studies of CIBINQO for atopic dermatitis [*see Adverse Reactions (6.1)*].

In a large, randomized, postmarketing safety study of another JAK inhibitor in RA patients 50 years of age and older with at least one cardiovascular risk factor, a higher rate of major adverse cardiovascular events (MACE) defined as cardiovascular death, non-fatal myocardial infarction (MI), and non-fatal stroke was observed with the JAK inhibitor compared to those treated with TNF blockers. CIBINQO is not approved for use in RA. Patients who are current or past smokers are at additional increased risk.

Consider the benefits and risks for the individual patient prior to initiating or continuing therapy with CIBINQO, particularly in patients who are current or past smokers and patients with other cardiovascular risk factors. Patients should be informed about the symptoms of serious cardiovascular events and the steps to take if they occur. Discontinue CIBINQO in patients that have experienced a myocardial infarction or stroke.

5.5 Thrombosis

Deep venous thrombosis (DVT) and pulmonary embolism (PE) were observed in patients receiving CIBINQO in the clinical studies for atopic dermatitis [*see Adverse Reactions (6.1)*].

Thrombosis, including DVT, PE, and arterial thrombosis have been reported in patients receiving JAK inhibitors used to treat inflammatory conditions. Many of these adverse reactions were serious and some resulted in death.

In a large, randomized, postmarketing safety study of another JAK inhibitor in RA patients 50 years of age and older with at least one cardiovascular risk factor, higher rates of overall thrombosis, DVT, and PE were observed compared to those treated with TNF blockers. CIBINQO is not approved for use in RA.

Avoid CIBINQO in patients that may be at increased risk of thrombosis. If symptoms of thrombosis occur, discontinue CIBINQO and evaluate and treat patients appropriately.

5.6 Laboratory Abnormalities

Hematologic Abnormalities

Treatment with CIBINQO was associated with an increased incidence of thrombocytopenia and lymphopenia [see *Adverse Reactions (6.1)*]. Prior to CIBINQO initiation, perform a CBC [see *Dosage and Administration (2.1)*]. CBC evaluations are recommended at 4 weeks after initiation and 4 weeks after dose increase of CIBINQO. Discontinuation of CIBINQO therapy is required for certain laboratory abnormalities [see *Dosage and Administration (2.6)*].

Lipid Elevations

Dose-dependent increase in blood lipid parameters were reported in patients treated with CIBINQO [see *Adverse Reactions (6.1)*]. Lipid parameters should be assessed approximately 4 weeks following initiation of CIBINQO therapy and thereafter patients should be managed according to clinical guidelines for hyperlipidemia. The effect of these lipid parameter elevations on cardiovascular morbidity and mortality has not been determined.

5.7 Immunizations

Prior to initiating CIBINQO, complete all age-appropriate vaccinations as recommended by current immunization guidelines including prophylactic herpes zoster vaccinations. Avoid vaccination with live vaccines immediately prior to, during, and immediately after CIBINQO therapy.

6 ADVERSE REACTIONS

The following clinically significant adverse reactions are described elsewhere in the labeling:

- Serious Infections [see *Warnings and Precautions (5.1)*]
- Mortality [see *Warnings and Precautions (5.2)*]
- Malignancy and Lymphoproliferative Disorders [see *Warnings and Precautions (5.3)*]
- Major Adverse Cardiovascular Events [see *Warnings and Precautions (5.4)*]
- Thrombosis [see *Warnings and Precautions (5.5)*]
- Laboratory Abnormalities [see *Warnings and Precautions (5.6)*]

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

The safety of CIBINQO was evaluated in four randomized, placebo-controlled clinical trials (2 monotherapy, 1 combination therapy with topical corticosteroid, and 1 dose-ranging) and one long-term extension trial in subjects with moderate to severe atopic dermatitis (AD). A total of 1623 subjects with moderate to severe atopic dermatitis were treated with CIBINQO in these clinical trials representing 1428 patient-years of exposure. There were 634 subjects with at least 1 year of exposure to CIBINQO.

In the placebo-controlled clinical trials, a total of 1198 subjects were exposed to CIBINQO with 608 subjects receiving CIBINQO 100 mg once daily and 590 subjects receiving CIBINQO 200 mg once daily for up to

16 weeks. The median age of subjects was 33.0 years, 124 subjects (8.1%) were 12 to less than 18 years old and 94 subjects (6.1%) were 65 years of age or older. The majority of subjects were White (68.7%) and male (53.9%). While subjects aged 12 to 17 years were included in these trials, CIBINQO is not approved for use in pediatric subjects [see *Use in Specific Populations* (8.4)].

Adverse reactions occurring at $\geq 1\%$ in any of the treated groups and at a higher rate than in the placebo group are presented in Table 3. A total of 61 (5.1%) subjects treated with CIBINQO were discontinued from the trials due to adverse reactions. The safety profile of CIBINQO in the monotherapy and the combination trial(s) were similar.

Table 3. Adverse Reactions from Placebo-Controlled Trials Reported in $\geq 1\%$ of CIBINQO Treated Subjects with Moderate to Severe Atopic Dermatitis and at Higher Rate than Placebo for up to 16 Weeks

	Weeks 0-16		
	CIBINQO 200 mg N=590 n (% ^a)	CIBINQO 100 mg N=608 n (% ^a)	Placebo N=342 n (% ^a)
Nasopharyngitis	51 (8.7)	75 (12.4)	27 (7.9)
Nausea	86 (14.5)	37 (6.0)	7 (2.1)
Headache	46 (7.8)	36 (6.0)	12 (3.5)
Herpes simplex ^b	25 (4.2)	20 (3.3)	6 (1.8)
Increased blood creatinine phosphokinase	17 (2.9)	14 (2.3)	5 (1.5)
Dizziness	17 (2.9)	11 (1.8)	3 (0.9)
Urinary tract infection	13 (2.2)	10 (1.7)	4 (1.2)
Fatigue	8 (1.3)	10 (1.6)	2 (0.5)
Acne	28 (4.7)	10 (1.6)	0 (0.0)
Vomiting	19 (3.2)	9 (1.5)	3 (0.9)
Impetigo	3 (0.5)	9 (1.5)	1 (0.3)
Oropharyngeal pain	6 (1.0)	8 (1.4)	2 (0.6)
Hypertension	5 (0.8)	7 (1.2)	2 (0.7)
Influenza	6 (1.1)	7 (1.2)	0 (0.0)
Gastroenteritis	8 (1.3)	7 (1.1)	2 (0.6)
Dermatitis contact	3 (0.5)	6 (1.1)	1 (0.3)
Abdominal pain upper	11 (1.9)	4 (0.6)	0 (0.0)
Abdominal discomfort	7 (1.2)	3 (0.5)	1 (0.3)
Herpes zoster	7 (1.2)	2 (0.3)	0 (0.0)
Thrombocytopenia	9 (1.5)	0 (0.0)	0 (0.0)

^a Study size adjusted percentages

^b Herpes simplex also includes oral herpes, ophthalmic herpes, herpes dermatitis, genital herpes.

Specific Adverse Reactions

Exposure adjusted incidence rates were adjusted by trial size for all the adverse reactions reported in this section.

Overall Infections

In the placebo-controlled trials, for up to 16 weeks, overall infections were reported in 90 subjects (126.8 per 100 patient-years) treated with placebo, 211 subjects (168.8 per 100 patient-years) treated with CIBINQO 100 mg and 204 subjects (159.5 per 100 patient-years) treated with CIBINQO 200 mg. In all 5 clinical trials,

including the long-term extension trial, overall infections were reported in 427 subjects (91.8 per 100 patient-years) treated with CIBINQO 100 mg and 394 subjects (103.2 per 100 patient-years) treated with CIBINQO 200 mg.

Serious Infections

In the placebo-controlled trials, for up to 16 weeks, serious infections were reported in 2 subjects (2.6 per 100 patient-years) treated with placebo, 6 subjects (3.9 per 100 patient-years) treated with CIBINQO 100 mg, and 2 subjects (1.3 per 100 patient-years) treated with CIBINQO 200 mg. In all 5 clinical trials, including the long-term extension trial, serious infections were reported in 18 subjects (2.3 per 100 patient-years) treated with CIBINQO 100 mg and 16 subjects (2.3 per 100 patient-years) treated with CIBINQO 200 mg. The most commonly reported serious infections were herpes simplex, herpes zoster, and pneumonia.

Herpes Zoster

In the placebo-controlled trials, for up to 16 weeks, opportunistic infections were generally cases of multidermatomal cutaneous herpes zoster. Herpes zoster was reported in 0 subjects treated with placebo, 3 subjects (1.9 per 100 patient-years) treated with CIBINQO 100 mg and 8 subjects (5.1 per 100 patient-years) treated with CIBINQO 200 mg. In all 5 clinical trials, including the long-term extension trial, herpes zoster was reported in 16 subjects (2.0 per 100 patient-years) treated with CIBINQO 100 mg and 35 subjects (5.2 per 100 patient-years) treated with CIBINQO 200 mg.

Malignancy

In the placebo-controlled trials, for up to 16 weeks, no malignancy was reported in subjects treated with placebo or CIBINQO 100 mg and in 1 patient (0.65 per 100 patient-years) treated with CIBINQO 200 mg. In all 5 clinical trials, including the long-term extension trial, malignancy was reported in 4 subjects (0.5 per 100 patient-years) treated with CIBINQO 100 mg and 2 subjects (0.3 per 100 patient-years) treated with CIBINQO 200 mg.

Thrombosis

In all clinical trials, including the long-term extension trial, pulmonary embolism was reported in 3 subjects (0.4 per 100 patient-years), who were treated with CIBINQO 200 mg. Deep vein thrombosis was reported in 2 subjects (0.3 per 100 patient-years) who were treated with CIBINQO 200 mg. No thrombosis occurred in subjects treated with CIBINQO 100 mg.

Major Adverse Cardiovascular Events

In the placebo-controlled trials, for up to 16 weeks, major adverse cardiovascular event (MACE) was reported in 1 subject (0.6 per 100 patient-years) treated with CIBINQO 100 mg. In all 5 clinical trials, including the long-term extension trial, MACE was reported in 1 patient (0.1 per 100 patient-years) treated with CIBINQO 100 mg and 2 subjects (0.3 per 100 patient-years) treated with CIBINQO 200 mg.

Thrombocytopenia

In the placebo-controlled trials, for up to 16 weeks, treatment with CIBINQO was associated with a dose-related decrease in platelet count. Maximum effects on platelets were observed within 4 weeks, after which the platelet count returned towards baseline despite continued therapy. In all 5 clinical trials, including the long-term extension trial 6 subjects (0.9 per 100 patient-years) treated with CIBINQO 200 mg had adverse reactions of thrombocytopenia, no subjects treated with CIBINQO 100 mg had an adverse reaction of thrombocytopenia.

Lymphopenia

In the placebo-controlled trials, for up to 16 weeks, confirmed ALC $<500/\text{mm}^3$ occurred in 2 subjects (1.2 per 100 patient-years) treated with CIBINQO 200 mg and 0 subjects treated with CIBINQO 100 mg or placebo. Both cases occurred in the first 4 weeks of exposure.

Lipid Elevations

In the placebo-controlled trials, for up to 16 weeks, there was a dose-related percent increase in low-density lipoprotein cholesterol (LDL-c), total cholesterol, and high-density lipoprotein cholesterol (HDL-c) relative to placebo at Week 4 which remained elevated through the final visit in the treatment period. Adverse reactions related to hyperlipidemia occurred in 1 subject (0.6 per 100 patient-years) exposed to CIBINQO 100 mg, 3 subjects (2.0 per 100 patient-years) exposed to CIBINQO 200 mg.

Retinal Detachment

In the placebo-controlled trials, for up to 16 weeks, retinal detachment occurred in 1 subject (0.6 per 100 patient-years) treated with CIBINQO 100 mg. In all 5 clinical trials, including the long-term extension trial, retinal detachment occurred in 2 subjects (0.3 per 100 patient-years) treated with CIBINQO 100 mg.

Creatine Phosphokinase Elevations (CPK)

In the placebo-controlled trials, for up to 16 weeks, events of blood CPK increased were reported in 6 subjects (7.5 per 100 patient-years) treated with placebo, 11 subjects (6.9 per 100 patient-years) treated with 100 mg of CIBINQO and 19 subjects (12.3 per 100 patient-years) treated with 200 mg of CIBINQO. Most elevations were transient, there were no reported adverse reactions of rhabdomyolysis.

7 DRUG INTERACTIONS

7.1 Effects of Other Drugs on CIBINQO

Table 4 includes drugs with clinically significant drug interactions affecting CIBINQO.

Table 4. Clinically Significant Drug Interactions Affecting CIBINQO

Strong CYP2C19 Inhibitors	
<i>Clinical Impact</i>	Coadministration of CIBINQO with strong CYP2C19 inhibitors increases the combined exposure of abrocitinib and its two active metabolites, M1 and M2 which may increase the adverse reactions of CIBINQO [see <i>Clinical Pharmacology</i> (12.3)].
<i>Intervention</i>	Dosage reduction of CIBINQO is recommended when coadministered with strong CYP2C19 inhibitors [see <i>Dosage and Administration</i> (2.5)].
Moderate to Strong Inhibitors of both CYP2C19 and CYP2C9	
<i>Clinical Impact</i>	Coadministration of CIBINQO with drugs that are moderate to strong inhibitors of both CYP2C19 and CYP2C9 increases the exposure of abrocitinib and its two active metabolites, M1 and M2 which may increase the adverse reactions of CIBINQO [see <i>Clinical Pharmacology</i> (12.3)].
<i>Intervention</i>	Avoid concomitant use of CIBINQO with drugs that are moderate to strong inhibitors of both CYP2C19 and CYP2C9.
Strong CYP2C19 or CYP2C9 Inducers	
<i>Clinical Impact</i>	Coadministration of CIBINQO with strong CYP2C19 or CYP2C9 inducers decreases the combined exposure of abrocitinib and its two active metabolites, M1 and M2, which may result in loss of or reduced clinical response [see <i>Clinical Pharmacology</i> (12.3)].
<i>Intervention</i>	Avoid concomitant use of CIBINQO with strong CYP2C19 or CYP2C9 inducers.

7.2 Effects of CIBINQO on Other Drugs

Table 5 includes clinically significant drug interactions affecting other drugs.

Table 5. Clinically Significant Interactions Affecting Other Drugs

P-gp Substrate Where Small Concentration Changes May Lead to Serious or Life-threatening Toxicities	
<i>Clinical Impact</i>	Coadministration of CIBINQO with P-gp substrate increases plasma concentrations of P-gp substrates and may result in potential adverse reactions of the P-gp substrate where small concentration changes may lead to serious or life-threatening toxicities (e.g., digoxin) [see <i>Clinical Pharmacology</i> (12.3)].
<i>Intervention</i>	Monitor appropriately or dose titrate P-gp substrate where small concentration changes may lead to serious or life-threatening toxicities when coadministered with CIBINQO.
Antiplatelet Therapy Drugs	
<i>Clinical Impact</i>	Coadministration of CIBINQO with antiplatelet therapy drugs may increase the risk of bleeding with thrombocytopenia [see <i>Warnings and Precautions</i> (5.5) and <i>Clinical Pharmacology</i> (12.2)].
<i>Intervention</i>	Antiplatelet drugs, except for low-dose aspirin (≤ 81 mg daily), during the first 3 months of treatment are contraindicated with CIBINQO [see <i>Contraindications</i> (4)].

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Pregnancy Exposure Registry

There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to CIBINQO during pregnancy. Pregnant women exposed to CIBINQO and health care providers are encouraged to call 1-877-311-3770.

Risk Summary

Available data from pregnancies reported in clinical trials with CIBINQO are not sufficient to establish a drug-associated risk for major birth defects, miscarriage, or other adverse maternal or fetal outcomes. In animal reproduction studies, oral administration of abrocitinib to pregnant rats and rabbits during organogenesis at exposure 14 or 5 times the maximum recommended human dose (MRHD) based on AUC comparison, respectively, resulted in maternal dystocia and skeletal variations in rats and no adverse effects in rabbits (*see Data*).

The background risks of major birth defects and miscarriage for the indicated population are unknown. All pregnancies carry some risk of birth defects, loss, or other adverse outcomes. The background risks in the U.S. general population of major birth defects and miscarriages are 2-4% and 15-20% of clinically recognized pregnancies, respectively.

Data

Animal Data

In an embryofetal development study, abrocitinib was administered orally to pregnant rats at doses of 10, 30, or 60 mg/kg/day during the period of organogenesis. No fetal malformations were observed. Abrocitinib increased the incidence of skeletal variations of short 13th ribs at 30 mg/kg/day (14 times the MRHD based on AUC comparison). Increased embryofetal lethality and additional skeletal variations (cervical arches with reduced ventral processes, thickened ribs, and unossified metatarsals) were noted at 60 mg/kg/day (22 times the MRHD based on AUC comparison).

In an embryofetal development study, abrocitinib was administered orally to pregnant rabbits at doses of 10, 30, or 75 mg/kg/day during the period of organogenesis. No abrocitinib-related maternal or developmental toxicity was noted at doses up to 75 mg/kg/day (5 times the MRHD based on AUC comparison).

In a prenatal and postnatal development study, abrocitinib was administered orally to pregnant rats at doses of 10, 30, and 60 mg/kg/day beginning on gestation day 6 and continuing through lactation day 20. Dystocia with prolonged parturition and reduced offspring body weights were noted at 30 mg/kg/day (14 times the MRHD based on AUC comparison). Postnatal survival was markedly decreased at 60 mg/kg/day (22 times the MRHD based on AUC comparison). No maternal toxicity was observed at 10 mg/kg/day (3 times the MRHD based on AUC comparison). No abrocitinib-related effects on postnatal developmental, neurobehavioral, or reproductive performance of offspring was noted at doses up to 30 mg/kg/day (14 times the MRHD based on AUC comparison).

8.2 Lactation

Risk Summary

There are no data on the presence of abrocitinib in human milk, the effects on the breast-fed infant, or the effects on milk production. Abrocitinib was secreted in milk of lactating rats (*see Data*). When a drug is present in animal milk, it is likely that the drug will be present in human milk. Because of the serious adverse findings in adults, including risks of serious infections, malignancy, and thrombosis, advise women not to breastfeed during treatment with CIBINQO and for one day after the last dose (approximately 5-6 elimination half-lives).

Data

Animal Data

Lactating female rats were orally administered a single dose of 10 mg/kg abrocitinib on lactation day 12. Abrocitinib AUC was approximately 5 times greater in milk than in plasma.

8.3 Females and Males of Reproductive Potential

Infertility

Females

Based on the findings in rats, oral administration of CIBINQO may impair female fertility. Impaired fertility in female rats was reversible 1 month after cessation of abrocitinib oral administration [*see Nonclinical Toxicology (13.1)*].

8.4 Pediatric Use

The safety and effectiveness of CIBINQO have not been established in pediatric patients.

Juvenile Animal Toxicity Data

In a juvenile animal toxicity study, abrocitinib was administered orally to juvenile rats at doses of 5, 25, and 75 mg/kg/day beginning on postnatal day 10 (approximately equivalent to a human infant) and continuing through postnatal day 63 (approximately equivalent to an adolescent). Abrocitinib caused a reversible, dose-related decrease in the primary spongiosa in the metaphysis of the proximal tibia and distal femur. Abrocitinib produced adverse effects on bone development at all dose levels. Abrocitinib caused irreversible dose-related small or misshapen femoral heads at doses ≥ 5 mg/kg/day (1.1 times the MRHD based on AUC comparison).

Abrocitinib also irreversibly decreased femur size and caused paw malrotation and limb impairment at doses ≥ 25 mg/kg/day (10 times the MRHD based on AUC comparison). At 75 mg/kg/day (36 times the MRHD based on AUC comparison), paw fractures generally corresponded to limb impairment, a fractured tibia was noted in a single female, and effects noted at lower doses were increased in frequency and severity. Irreversible bone findings have not been observed in older animals.

8.5 Geriatric Use

A total of 145 (4.6%) patients 65 years of age and older, while 25 (0.8%) were 75 years of age and older, were enrolled in CIBINQO clinical trials. Clinical trials of CIBINQO did not include sufficient numbers of patients 65 years of age and older to determine whether they respond differently from younger adult patients.

A higher proportion of patients 65 years of age and older discontinued from clinical trials compared to younger patients. Among all patients exposed to CIBINQO, including the long-term extension trial, confirmed ALC $< 500/\text{mm}^3$ occurred only in patients 65 years of age and older. A higher proportion of patients 65 years of age and older had platelet counts $< 75,000/\text{mm}^3$. The incidence rate of herpes zoster in patients 65 years of age and older treated with CIBINQO (7.40 per 100 patient-years) was higher than that of patients 18 to less than 65 years of age (3.44 per 100 patient-years).

8.6 Renal Impairment

In patients with severe (eGFR < 30 mL/min) and moderate (eGFR 30-59 mL/min) renal impairment, the combined exposure ($\text{AUC}_{\text{inf,u}}$) of abrocitinib and its two active metabolites, M1 and M2, is increased compared to patients with normal renal function (eGFR ≥ 90 mL/min) [see *Clinical Pharmacology* (12.3)]. This may increase the risk of adverse reactions such as infections.

CIBINQO is not recommended for use in patients with severe renal impairment and ESRD including those on renal replacement [see *Dosage and Administration* (2.3)].

A dosage reduction in patient with moderate renal impairment is recommended. No dosage adjustment is required in patients with mild renal impairment (eGFR 60-89 mL/min) [see *Dosage and Administration* (2.3)].

CIBINQO has not been studied in patients on renal replacement therapy. In Phase 3 clinical trials, CIBINQO was not evaluated in patients with atopic dermatitis with baseline creatinine clearance values less than 40 mL/min.

8.7 Hepatic Impairment

Avoid use of CIBINQO in patients with severe (Child Pugh C) hepatic impairment.

Dosage adjustment is not required in patients with mild (Child Pugh A) or moderate (Child Pugh B) hepatic impairment based on similar combined exposure ($\text{AUC}_{\text{inf,u}}$) of abrocitinib and its two active metabolites, M1 and M2 compared to patients with normal hepatic function. In clinical trials, CIBINQO was not evaluated in patients with severe (Child Pugh C) hepatic impairment [see *Clinical Pharmacology* (12.3)].

8.8 CYP2C19 Poor Metabolizers

In patients who are CYP2C19 poor metabolizers, the AUC of abrocitinib is increased compared to CYP2C19 normal metabolizers due to reduced metabolic clearance. Dosage reduction of CIBINQO is recommended in patients who are known or suspected to be CYP2C19 poor metabolizers based on genotype or previous

history/experience with other CYP2C19 substrates [see *Dosage and Administration (2.4)* and *Clinical Pharmacology (12.5)*].

10 OVERDOSAGE

There is no experience regarding human overdosage with CIBINQO. There is no specific antidote for overdose with CIBINQO. In case of an overdose, call Poison Control Center at 1-800-222-1222 for latest recommendations.

11 DESCRIPTION

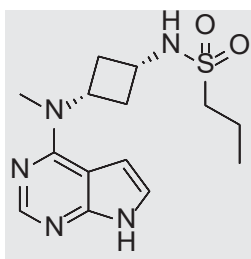
CIBINQO (abrocitinib) tablets contain the free base of abrocitinib, a Janus kinase (JAK) inhibitor, for oral administration.

Abrocitinib is a white to pale colored powder with the following chemical name:

N-((1*s*,3*s*)-3-(methyl(7*H*-pyrrolo[2,3-*d*]pyrimidin-4-yl)amino)cyclobutyl)propane-1-sulfonamide

The solubility of abrocitinib in water is 0.04 mg/mL at 25°C.

Abrocitinib has a molecular weight of 323.42 g/mol and a molecular formula of C₁₄H₂₁N₅O₂S. The structural formula of abrocitinib is:



Each film-coated tablet contains 50 mg or 100 mg or 200 mg of abrocitinib and the following inactive ingredients: dibasic calcium phosphate anhydrous, hypromellose, iron oxide red, lactose monohydrate, Macrolog, magnesium stearate, microcrystalline cellulose, sodium starch glycolate, titanium dioxide, and triacetin.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

CIBINQO is a Janus kinase (JAK) inhibitor.

Abrocitinib reversibly inhibits JAK1 by blocking the adenosine triphosphate (ATP) binding site. In a cell-free isolated enzyme assay, abrocitinib was selective for JAK1 over JAK2 (28-fold), JAK3 (>340-fold), and tyrosine kinase (TYK) 2 (43-fold), as well as the broader kinome. The relevance of inhibition of specific JAK enzymes

to therapeutic effectiveness is not currently known. Both the parent compound and the active metabolites inhibit JAK1 activity *in vitro* with similar levels of selectivity.

12.2 Pharmacodynamics

Treatment with CIBINQO was associated with dose-dependent reduction in serum markers of inflammation, including high sensitivity C-reactive protein (hsCRP), interleukin-31 (IL-31) and thymus and activation regulated chemokine (TARC). These changes returned to near baseline within 4 weeks of drug discontinuation.

Effect on Platelet Count

Treatment with CIBINQO was also associated with a transient, dose-dependent decrease in platelet count with the nadir occurring at a median of 24 days after continuous administration of abrocitinib 200 mg once daily. The percent change from baseline of the nadir increases with decreasing baseline platelet counts (-41.2%, -33.4%, and -26.5% for baseline platelet counts of 170, 220, and 270 × 10³/mm³, respectively). Recovery of platelet count (~40% recovery by 12 weeks) occurred without discontinuation of the treatment.

Cardiac Electrophysiology

At a dose 3 times the maximum approved recommended dose, abrocitinib does not prolong the QT interval to any clinically relevant extent.

12.3 Pharmacokinetics

Abrocitinib plasma C_{max} and AUC increased dose proportionally up to 200 mg. Steady-state plasma concentrations of abrocitinib are achieved within 48 hours after once daily administration.

Absorption

Abrocitinib is absorbed with over 91% extent of oral absorption and absolute oral bioavailability of approximately 60%. The peak plasma concentrations of abrocitinib are reached within 1 hour.

Effect of Food

Coadministration of CIBINQO with a high-fat, high-calorie meal (total 916 calories, with approximate distribution of 55% fat, 29% carbohydrates, and 16% protein) had no clinically relevant effect on abrocitinib exposures (AUC and C_{max} of abrocitinib increased by approximately 26% and 29%, respectively, and T_{max} was prolonged by 2 hours) [see *Dosage and Administration* (2.7)].

Distribution

After intravenous administration, the volume of distribution of abrocitinib is approximately 100 L. Approximately 64%, 37% and 29% of circulating abrocitinib and its active metabolites M1 and M2, respectively, are bound to plasma proteins. Abrocitinib and its active metabolites M1 and M2 bind predominantly to albumin and distribute equally between red blood cells and plasma.

Elimination

Abrocitinib is eliminated primarily by metabolic clearance mechanisms. The mean elimination half-lives of abrocitinib and its two active metabolites, M1 and M2, range 3 to 5 hours.

Metabolism

The metabolism of abrocitinib is mediated by multiple CYP enzymes, CYP2C19 (~53%), CYP2C9 (~30%), CYP3A4 (~11%) and CYP2B6 (~6%). In a human radiolabeled study, abrocitinib was the most prevalent circulating species, with two active polar mono-hydroxylated metabolites identified as M1 (3-hydroxypropyl), and M2 (2-hydroxypropyl). Metabolite M1 is less active than abrocitinib while metabolite M2 is as active as the parent. The pharmacologic activity of abrocitinib is attributable to the unbound exposure of parent molecule (~60%) as well as M1 (~10%) and M2 (~30%) in systemic circulation. The sum of unbound exposures of abrocitinib, M1 and M2, each expressed in molar units and adjusted for relative potencies, is referred to as the combined exposure of abrocitinib and its two active metabolites, M1 and M2.

Excretion

After a single radiolabeled abrocitinib dose, less than 1% of the dose was excreted in urine as unchanged drug. The metabolites of abrocitinib, M1 and M2 are excreted predominantly in urine, and are substrates of OAT3 transporter.

Specific Populations

Body weight, sex, race, and age did not have a clinically meaningful effect on CIBINQO exposure.

Patients with Renal Impairment

In a renal impairment study, subjects with severe (eGFR <30 mL/min as estimated by MDRD equation) and moderate (eGFR 30-59 mL/min, MDRD) renal impairment had approximately 191% and 110% increase in the combined exposure ($AUC_{inf,u}$) of abrocitinib and its active metabolites, M1 and M2, respectively, compared to subjects with normal renal function (eGFR \geq 90 mL/min, MDRD). Based on these results, a clinically significant increase in the combined exposure of abrocitinib and its active metabolites, M1 and M2, is not expected in subjects with mild renal impairment (eGFR 60 -89 mL/min, MDRD) [see *Dosage and Administration* (2.3) and *Use in Specific Population* (8.6)].

CIBINQO has not been studied in subjects on renal replacement therapy [see *Dosage and Administration* (2.3) and *Use in Specific Population* (8.6)]. In Phase 3 clinical studies, CIBINQO was not evaluated in subjects with atopic dermatitis with baseline creatinine clearance values less than 40 mL/min.

Patients with Hepatic Impairment

Subjects with mild hepatic impairment (Child Pugh A) had approximately 4% decrease in the combined exposure ($AUC_{inf,u}$) of abrocitinib and its two active metabolites, M1 and M2, compared to subjects with normal hepatic function. Subjects with moderate hepatic impairment (Child Pugh B) had approximately 15% increase in the combined exposure ($AUC_{inf,u}$) of abrocitinib and its two active metabolites, M1 and M2, compared to subjects with normal hepatic function. These changes are not clinically significant. In clinical studies, CIBINQO has not been studied in subjects with severe (Child Pugh C) hepatic impairment, or in subjects

screened positive for active hepatitis B or hepatitis C [see *Use in Specific Populations* (8.7) and *Warnings and Precautions* (5.1)].

Drug Interaction Studies

Clinical Studies

The effect of coadministered drugs on the pharmacokinetics of abrocitinib is presented in Table 6.

Table 6. Change in Pharmacokinetics of the Combined Exposure of Abrocitinib and its Two Active Metabolites (M1 and M2) in the Presence of Coadministered Drugs

Coadministered Drugs	Regimen of Coadministered Drug	Dose of Abrocitinib	Ratio ^a (90% Confidence Interval)	
			C _{max,u}	AUC _{inf,u}
Strong CYP2C19 and moderate CYP3A inhibitor: Fluvoxamine [see <i>Drug Interactions</i> (7.1)]	50 mg once daily x 9 days	100 mg	1.33 (1.00-1.78)	1.91 (1.74-2.10)
Strong CYP2C19, moderate CYP2C9 and CYP3A inhibitor: Fluconazole [see <i>Drug Interactions</i> (7.1)]	400 mg on Day 1 and 200 mg on Days 2-7	100 mg	1.23 (1.08-1.42)	2.55 ^b (2.42-2.69)
Strong CYP Enzymes Inducers: Rifampin [see <i>Drug Interactions</i> (7.1)]	600 mg once daily x 8 days	200 mg	0.69 (0.50-0.94)	0.44 (0.41-0.47)
OAT3 inhibitor: Probenecid ^c	1,000 mg twice daily x 3 days	200 mg	1.30 (1.04-1.63)	1.66 (1.52-1.80)

^a Ratios for C_{max,u} and AUC_{inf,u} compare coadministration of the drug with abrocitinib versus administration of abrocitinib alone.

^b When coadministered with Fluconazole, the systemic exposure of abrocitinib was approximately 4.8-fold higher compared to when abrocitinib is administered alone.

^c Drug interaction with OAT3 inhibitor is not clinically significant.

The effect of abrocitinib on the pharmacokinetics of coadministered drugs is presented in Table 7.

Table 7. Change in Pharmacokinetics of Coadministered Drugs in the Presence of Abrocitinib

Coadministered Drugs or In Vivo Markers of CYP Activity	Dose Regimen of Abrocitinib	Ratio ^a (90% Confidence Interval)	
		C _{max}	AUC _{inf}
Oral contraceptive: Ethinyl estradiol (EE) and levonorgestrel (LN)	200 mg once daily x 9 days	EE: 1.07 (0.99, 1.15) LN: 0.86 (0.75, 0.97)	EE: 1.19 (1.12, 1.26) LN ^b : 0.98 (0.87, 1.10)
Sensitive CYP3A Substrate: Midazolam	200 mg once daily x 7 days	0.93 (0.84, 1.04)	0.92 (0.86, 0.99)
Sensitive P-gp substrate: Dabigatran	200 mg single dose	1.40 (0.92, 2.13)	1.53 (1.09, 2.15)
Sensitive BCRP and OAT3 substrate: Rosuvastatin	200 mg once daily x 3 days	0.99 (0.86, 1.14)	1.02 (0.93, 1.12)
Sensitive MATE1/2K substrate: Metformin	200 mg once daily x 2 days	0.88 (0.81, 0.96)	0.93 (0.85, 1.03)

^a Ratios for C_{max} and AUC_{inf} compare coadministration of abrocitinib with the drug versus administration of the drug alone.

^b AUC_{last} of levonorgestrel was reported in lieu of AUC_{inf} because the terminal phase of levonorgestrel was not well characterized.

Coadministration of dabigatran etexilate (a P-gp substrate), with a single dose of CIBINQO 200 mg increased dabigatran AUC_{inf} and C_{max} by approximately 53% and 40%, respectively, compared with administration alone. These increases in dabigatran exposure are not considered clinically significant change. However, appropriate dose titration of P-gp substrate where small concentration changes may lead to serious or life-threatening toxicities (e.g., digoxin) when coadministered with the CIBINQO would be needed.

In Vitro Studies

Cytochrome P450 (CYP) Enzymes: Abrocitinib and its metabolites M1 and M2 are not inhibitors or inducers of CYP1A2, CYP2B6, CYP2C8, CYP2C9, CYP2C19, CYP2D6, or CYP3A4.

Uridine diphosphate (UDP)-glucuronosyl transferase (UGT) Enzymes: Abrocitinib and its metabolites M1 and M2 are not inhibitors or inducers of UGT1A1, UGT1A4, UGT1A6, UGT1A9, or UGT2B7.

Transporter Systems: Abrocitinib is an inhibitor of organic cation transporter (OCT)1 but is not an inhibitor of organic anion transporting polypeptide (OATP)1B1/1B3, bile salt export pump (BSEP), OAT1 or OCT2.

12.5 Pharmacogenomics

Patients who are CYP2C19 poor metabolizers have little to no CYP2C19 enzyme function compared to CYP2C19 normal metabolizers that have fully functional CYP2C19 enzymes.

After single doses of abrocitinib, CYP2C19 poor metabolizers demonstrated dose-normalized AUC of abrocitinib values that were 2.3-fold higher when compared to CYP2C19 normal metabolizers. Approximately 3-5% of Caucasians and Blacks and 15 to 20% of Asians are CYP2C19 poor metabolizers [see *Dosage and Administration* (2.4) and *Use in Specific Populations* (8.8)].

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

In a 2-year oral carcinogenicity study in rats, abrocitinib increased the incidence of benign thymomas in female rats at doses of 10 and 30 mg/kg/day (4 and 19 times the MRHD, respectively, based on AUC comparison). Abrocitinib was not carcinogenic in female rats at 3 mg/kg/day (0.8 times the MRHD based on AUC comparison) or male rats at doses up to 30 mg/kg/day (19 times the MRHD based on AUC comparison). Abrocitinib was not carcinogenic in Tg.rasH2 mice at oral doses up to 60 mg/kg/day in males and 75 mg/kg/day in females.

Abrocitinib was not mutagenic in the bacterial mutagenicity assay (Ames assay). Although abrocitinib was aneugenic in the in vitro TK6 micronucleus assay, abrocitinib was not aneugenic or clastogenic in an in vivo rat bone marrow micronucleus assay.

Abrocitinib did not impair male fertility at doses up to 70 mg/kg/day (35 times the MRHD based on AUC comparison) or female fertility at 10 mg/kg/day (3 times the MRHD based on AUC comparison). Abrocitinib impaired female fertility (reducing fertility index, corpora lutea, and implantation sites) at 70 mg/kg/day (39 times the MRHD based on AUC comparison). Impaired fertility in female rats reversed 1 month after cessation of abrocitinib administration.

14 CLINICAL STUDIES

The efficacy of CIBINQO as monotherapy and in combination with background topical corticosteroids were evaluated in 3 randomized, double-blind, placebo-controlled trials [Trial-AD-1 (NCT03349060), Trial-AD-2 (NCT03575871), and Trial-AD-3 (NCT03720470)] in 1615 subjects 12 years of age and older (CIBINQO is not approved for use in pediatric patients) with moderate-to-severe atopic dermatitis as defined by Investigator's Global Assessment (IGA) score ≥ 3 , Eczema Area and Severity Index (EASI) score ≥ 16 , body surface area (BSA) involvement $\geq 10\%$, and Peak Pruritus Numerical Rating Scale (PP-NRS) ≥ 4 at the baseline visit prior to randomization.

Overall, 53% of subjects were male, 69% of subjects were white, 64% of subjects had a baseline IGA score of 3 (moderate AD), and 36% of subjects had a baseline IGA score of 4 (severe AD). The baseline mean EASI score was 30. The baseline mean age was 36 years old with 8% of subjects 12 to less than 18 years old and 92% of subjects 18 years of age or older. Subjects in these trials were those who had inadequate response to previous topical therapy, or were subjects for whom topical treatments were medically inadvisable, or who had received systemic therapies including dupilumab. In each of the trials, over 40% of subjects had prior exposure to systemic therapy. In Trial-AD-1 and Trial-AD-2, 6% of the subjects had received dupilumab, whereas prior use of dupilumab was not allowed in Trial-AD-3.

Trial-AD-1, Trial-AD-2, and Trial-AD-3 assessed the co-primary endpoints of IGA and EASI-75 responses at Week 12. The designs of the trials are summarized in Table 8.

Table 8. Summary of Clinical Study Designs

Study Name (regimen type) Treatment Duration	Population (number of randomized and dosed subjects)	Treatment Arms	Co-Primary Endpoints
Trial-AD-1 (monotherapy) 12 weeks	*Subjects 12 years of age or older (387)	Oral administration of: • CIBINQO 200 mg QD • CIBINQO 100 mg QD • Placebo	<ul style="list-style-type: none"> IGA response^a at Week 12 EASI-75^b at Week 12
Trial-AD-2 (monotherapy) 12 weeks	*Subjects 12 years of age or older (391)	Oral administration of: • CIBINQO 200 mg QD • CIBINQO 100 mg QD • Placebo	
Trial-AD-3 (combination therapy) 16 weeks	Subjects 18 years of age or older (837)	Oral administration of: • CIBINQO 200 mg QD • CIBINQO 100 mg QD • Placebo Subcutaneous administration of: • Dupilumab 300 mg Q2W SC ^c All subjects received background topical corticosteroids	

Abbreviations: EASI=Eczema Area and Severity Index; IGA=Investigator's Global Assessment; QD=once daily; Q2W=once every 2 weeks.

- IGA response was based on IGA score of clear (0) or almost clear (1) (on a 5-point scale) and a reduction from baseline of ≥ 2 points.
- EASI-75 was based on $\geq 75\%$ improvement in EASI from baseline.
- Dupilumab treatment in Trial-AD-3: An initial dose of 600 mg on day 1, followed by 300 mg Q2W.

*Pediatric subjects 12 years of age and older were included in the trial population; however, CIBINQO is not approved for use in pediatric patients.

Clinical Response

Monotherapy Trials

The results of the CIBINQO monotherapy trials (Trial-AD-1 and Trial-AD-2) are presented in Table 9.

Table 9. Efficacy Results of CIBINQO Monotherapy at Week 12 in Subjects with Moderate-to-Severe AD (Trial-AD-1 and Trial-AD-2)

	Trial-AD-1			Trial-AD-2		
	CIBINQO		Placebo N=77	CIBINQO		Placebo N=78
	200 mg QD N=154	100 mg QD N=156		200 mg QD N=155	100 mg QD N=158	
IGA 0 or 1 ^a	44%	24%	8%	38%	28%	9%
Difference from Placebo (95% CI)	36% (26%, 46%)	16% (7%, 25%)	-	29% (19%, 39%)	19% (9%, 29%)	-
EASI-75 ^b	62%	40%	12%	61%	44%	10%
Difference from Placebo (95% CI)	51% (40%, 61%)	28% (18%, 39%)	-	50% (40%, 61%)	33% (23%, 44%)	-

Abbreviations: CI=confidence interval; EASI=Eczema Area and Severity Index; IGA=Investigator Global Assessment; QD=once daily.

- IGA responders were subjects with IGA score of clear (0) or almost clear (1) (on a 5-point scale) and a reduction from baseline of ≥ 2 points.
- EASI -75 responders were patients with $\geq 75\%$ improvement in EASI from baseline.

The proportion of subjects achieving PP-NRS4 at Week 2 (defined as an improvement of ≥ 4 points from baseline in PP-NRS) was higher in subjects treated with CIBINQO monotherapy 200 mg once daily (28% in Trial-AD-1 and 24% in Trial-AD-2) and 100 mg once daily (11% in both trials) compared to placebo (2% in both trials).

A higher proportion of subjects in the CIBINQO monotherapy 100 mg or 200 mg once daily arm compared to placebo achieved improvement in itching at Week 12.

Combination Therapy Trial

The results of CIBINQO in combination with background topical corticosteroids (Trial-AD-3) are presented in Table 10.

Table 10. Efficacy Results of CIBINQO with Concomitant Topical Corticosteroids at Week 12 in Subjects with Moderate-to-Severe AD (Trial-AD-3)

% Responders	CIBINQO		Placebo N=131
	200 mg QD N=226	100 mg QD N=238	
IGA 0 or 1 ^a at Week 12	47%	36%	14%
Difference from Placebo (95% CI)	34% (25%, 42%)	23% (15%, 31%)	-
EASI-75 ^b at Week 12	68%	58%	27%
Difference from Placebo (95% CI)	41% (32%, 51%)	32% (22%, 41%)	-

Abbreviations: CI=confidence interval; EASI=Eczema Area and Severity Index; IGA=Investigator Global Assessment; QD=once daily.

- IGA responders were subjects with IGA score of clear (0) or almost clear (1) (on a 5-point scale) and a reduction from baseline of ≥ 2 points.

b. EASI-75 responders were subjects with $\geq 75\%$ improvement in EASI, from baseline.

The proportions of subjects achieving PP-NRS4 at Week 2 was higher in subjects treated with CIBINQO 200 mg once daily (30%) and 100 mg once daily (14%) in combination with background medicated topical therapies compared to placebo (8%).

Examination of age, gender, race, weight and previous systemic AD therapy treatment did not identify differences in response to CIBINQO 100 mg or 200 mg once daily among these subgroups in Trial-AD-1, Trial-AD-2, and Trial-AD-3.

16 HOW SUPPLIED/STORAGE AND HANDLING

CIBINQO is supplied as:

Dosage Form	Strength	Description	Bottle Size (number of tablets)	NDC Number
Tablets	50 mg	Pink, oval tablet debossed with “PFE” on one side and “ABR 50” on the other.	30 count bottle	0069-0235-30
Tablets	100 mg	Pink, round tablet debossed with “PFE” on one side and “ABR 100” on the other.	30 count bottle	0069-0335-30
Tablets	200 mg	Pink, oval tablet debossed with “PFE” on one side and “ABR 200” on the other.	30 count bottle	0069-0435-30

Store CIBINQO at 20°C to 25°C (68°F to 77°F), excursions permitted between 15°C to 30°C (59°F to 86°F). Keep in original package. The container closure system is child resistant.

17 PATIENT COUNSELING INFORMATION

Advise the patient to read the FDA-approved patient labeling (Medication Guide).

Pregnancy Registry

Advise patients to report their pregnancy to 1-877-311-3770 [see *Use in Specific Populations* (8.1)].

Serious Infections

Inform patients that they may develop infections when taking CIBINQO. Instruct patients to tell their healthcare provider if they develop any signs or symptoms of an infection [see *Warnings and Precautions* (5.1)].

Advise patients that the risk of herpes zoster is increased in patients treated with CIBINQO and some cases can be serious [see *Warnings and Precautions* (5.1)].

Malignancies

Inform patients that CIBINQO may increase their risk of certain cancers, including skin cancers. Periodic skin examinations are recommended while using CIBINQO. Advise patients that exposure to sunlight and UV

light should be limited by wearing protective clothing and using a broad-spectrum sunscreen [see *Warnings and Precautions* (5.3)].

Major Adverse Cardiovascular Events

Inform patients that CIBINQO may increase their risk of major adverse cardiovascular events (MACE) including myocardial infarction, stroke, and cardiovascular death. Instruct all patients, especially current or past smokers or patients with other cardiovascular risk factors, to be alert for the development of signs and symptoms of cardiovascular events [see *Warnings and Precautions* (5.4)].

Thrombosis

Advise patients that events of DVT and PE have been reported in clinical trials with CIBINQO. Instruct patients to seek immediate medical attention if they develop any signs or symptoms of a DVT or PE [see *Warnings and Precautions* (5.5)].

Laboratory Abnormalities

Inform patients that CIBINQO may affect certain lab tests, and that blood tests are required before and during CIBINQO treatment [see *Dosage and Administration* (2.1) and *Warnings and Precautions* (5.6)].

Immunizations

Advise patients that vaccination with live vaccines is not recommended during CIBINQO treatment and immediately prior to or after CIBINQO treatment. Instruct patients to inform the healthcare practitioner that they are taking CIBINQO prior to a potential vaccination [see *Warnings and Precautions* (5.7)].

Retinal Detachment

Inform patients that retinal detachment has been reported in clinical trials for atopic dermatitis in patients who received CIBINQO. Advise patients to immediately inform their healthcare provider if they develop any sudden changes in vision while receiving CIBINQO [see *Adverse Reactions* (6.1)].

Infertility

Advise females of reproductive potential that CIBINQO may impair fertility [see *Use in Specific Populations* (8.3)].

Lactation

Advise a woman not to breastfeed during treatment with CIBINQO [see *Use in Specific Populations* (8.2)].

Administration

Advise patients not to chew, crush, or split CIBINQO tablets [see *Dosage and Administration* (2.7)].

This product's labeling may have been updated. For the most recent prescribing information, please visit www.pfizer.com.

For Medical Information about CIBINQO, please visit www.pfizermedinfo.com or call 1-800-438-1985.



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New York, NY 10017

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Medication Guide
CIBINQO (Si BINK oh)
(abrocitinib)
tablets, for oral use

What is the most important information I should know about CIBINQO?

CIBINQO may cause serious side effects, including:

1. Serious infections

CIBINQO is a medicine that affects your immune system. CIBINQO can lower the ability of your immune system to fight infections. Some people have had serious infections while taking CIBINQO or other similar medicines, including tuberculosis (TB), and infections caused by bacteria, fungi, or viruses that can spread throughout the body. Some people have died from these infections.

- Your healthcare provider should test you for TB before starting treatment with CIBINQO.
- Your healthcare provider should watch you closely for signs and symptoms of TB during treatment with CIBINQO.

You should not start taking CIBINQO if you have any kind of infection unless your healthcare provider tells you it is okay.

You may be at a higher risk of developing shingles (herpes zoster).

Before starting CIBINQO, tell your healthcare provider if you:

- are being treated for an infection.
- have had an infection that does not go away or that keeps coming back.
- have diabetes, chronic lung disease, HIV, or a weak immune system.
- have TB or have been in close contact with someone with TB.
- have had shingles (herpes zoster).
- have had hepatitis B or hepatitis C.
- live or have lived or have traveled to certain parts of the country (such as the Ohio and Mississippi River valleys and the Southwest) where there is an increased chance for getting certain kinds of fungal infections. These infections may happen or become more severe if you use CIBINQO. Ask your healthcare provider if you do not know if you have lived in an area where these infections are common.
- think you have an infection or have symptoms of an infection such as:
 - fever, sweating, or chills
 - muscle aches
 - cough or shortness of breath
 - blood in your phlegm
 - weight loss
 - warm, red, or painful skin or sores on your body
 - diarrhea or stomach pain
 - burning when you urinate or urinating more often than usual
 - feeling very tired

After starting CIBINQO, call your healthcare provider right away if you have any symptoms of an infection. CIBINQO can make you more likely to get infections or make any infections that you have worse.

2. Increased risk of death in people 50 years of age and older who have at least 1 heart disease (cardiovascular) risk factor and are taking a medicine in the class of medicines called Janus kinase (JAK) inhibitors. CIBINQO is a JAK inhibitor medicine.

3. Cancer and immune system problems

CIBINQO may increase your risk of certain cancers by changing the way your immune system works.

- Lymphoma and other cancers, including skin cancers, can happen in people taking CIBINQO.
- People taking a medicine in the class of medicines called Janus kinase (JAK) inhibitors have a higher risk of certain cancers including lymphoma and lung cancer, especially if you are a current or past smoker.
- Follow your healthcare provider's advice about having your skin checked for skin cancer during treatment with CIBINQO. Limit the amount of time you spend in sunlight. Avoid using tanning beds or sunlamps. Wear protective clothing when you are in the sun and use a sunscreen with a high protection factor (SPF 30 and above). This is especially important if your skin is very fair or if you have a family history of skin cancer.

Tell your healthcare provider if you have ever had any type of cancer.

4. Increased risk of major cardiovascular events such as heart attack, stroke or death in people 50 years of age and older who have at least 1 heart disease (cardiovascular) risk factor and taking a medicine in the class of medicines called JAK inhibitors, especially if you are a current or past smoker.

Some people taking CIBINQO have had major cardiovascular events.

Get emergency help right away if you develop any symptoms of a heart attack or stroke during treatment with CIBINQO, including:

- discomfort in the center of your chest that lasts for more than a few minutes, or that goes away and comes back
- severe tightness, pain, pressure, or heaviness in your chest, throat, neck, or jaw
- pain or discomfort in your arms, back, neck, jaw, or stomach
- weakness in one part or on one side of your body
- slurred speech
- shortness of breath with or without chest discomfort
- breaking out in a cold sweat
- nausea or vomiting
- feeling lightheaded

5. Blood clots

Blood clots in the veins of your legs (deep vein thrombosis, DVT) or lungs (pulmonary embolism, PE) can happen in some people taking CIBINQO. This may be life-threatening. Blood clots in the veins of the legs (deep vein thrombosis, DVT) and lungs (pulmonary embolism, PE) have happened more often in people who are 50 years of age and older and with at least 1 heart disease (cardiovascular) risk factor taking a medicine in the class of medicines called Janus kinase (JAK) inhibitors.

- Tell your healthcare provider if you have had blood clots in the veins of your legs or lungs in the past.
- Get medical help right away if you have any signs and symptoms of blood clots during treatment with CIBINQO, including:
 - swelling, pain or tenderness in one or both legs
 - sudden, unexplained chest or upper back pain
 - shortness of breath or difficulty breathing

6. Changes in certain laboratory test results

Your healthcare provider should do blood tests before you start taking CIBINQO and during treatment with CIBINQO to check for the following:

- **low lymphocyte count.** Lymphocytes are white blood cells that help the body fight off infections.
- **low neutrophil count.** Neutrophils are white blood cells that help the body fight off infections.
- **low red blood cell count.** This may mean that you have anemia, which may make you feel weak and tired.
- **low platelet count.** Platelets help form clots and stop or prevent bleeding.

You should not take CIBINQO if your lymphocyte counts, neutrophil counts, red blood cell counts, or platelet counts are too low. Your healthcare provider may stop your CIBINQO treatment for a period of time if needed because of changes in these blood test results. You may also have changes in other laboratory tests, such as your blood cholesterol levels.

Your healthcare provider should do blood tests about 4 weeks after you start taking CIBINQO, and 4 weeks after any increase in your dose of CIBINQO to check your blood cell counts, and as often as needed for your other laboratory tests.

See **“What are the possible side effects of CIBINQO?”** for more information about side effects.

What is CIBINQO?

CIBINQO is a prescription medicine that is a Janus Kinase (JAK) inhibitor. CIBINQO is used to treat adults with moderate-to-severe atopic dermatitis (eczema) that did not respond to other treatment and is not well controlled with prescription therapies, including biologic medicines or in adults who cannot tolerate these therapies.

It is not known if CIBINQO is safe and effective in children.

During the first 3 months of treatment with CIBINQO, do not take CIBINQO with other medicines that prevent blood clots. You can take low-dose aspirin up to a dose of 81 mg each day during this time if prescribed by your healthcare provider.

Before taking CIBINQO, tell your healthcare provider about all of your medical conditions, including if you:

- See **“What is the most important information I should know about CIBINQO?”**
- have an infection.
- are a current or past smoker
- have had a heart attack, other heart problems, or stroke
- have kidney problems or liver problems.
- have low platelet counts or white blood cell counts.
- have any eye problems, including cataracts or retinal detachment.
- have recently received or are scheduled to receive an immunization (vaccine). People who take CIBINQO should not receive live vaccines.
- are pregnant or plan to become pregnant. It is not known if CIBINQO will harm your unborn baby.
 - **Pregnancy Exposure Registry.** Pfizer has a registry for women who take CIBINQO during pregnancy. The purpose of this registry is to check the health of you and your baby. If you are pregnant or become pregnant during treatment with CIBINQO, talk to your healthcare provider about how you can join this pregnancy registry, or you may contact the registry at 1-877-311-3770 or www.cibinqopregnancyregistry.com.
- are breastfeeding or plan to breastfeed. It is not known if CIBINQO passes into your breast milk. You and your healthcare provider should decide if you will take CIBINQO or breastfeed. You should not do both.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. CIBINQO and other medicines may affect each other causing side effects.

Especially tell your healthcare provider if you take aspirin or any antiplatelet therapies. See **“Do not take CIBINQO if you.”** Ask your healthcare provider if you are unsure.

Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist whenever you get a new medicine.

How should I take CIBINQO?

- Take CIBINQO exactly as your healthcare provider tells you to take it.
- Take CIBINQO 1 time each day, at about the same time each day.
- Swallow CIBINQO tablets whole with water. Do not split, crush, or chew the tablets.
- You can take CIBINQO with or without food.
- CIBINQO can be used with or without prescribed topical medicines for atopic dermatitis. Prescribed topical medicine are lotions, creams, or ointments applied to your skin.
- If you miss a dose, take the dose as soon as possible. If it is less than 12 hours before the next dose, skip the dose. Take the next dose at your usually scheduled time.

- If you take too much CIBINQO, call the Poison Control Center at 1-800-222-1222 right away.

What are the possible side effects of CIBINQO?

CIBINQO may cause serious side effects, including:

- See **“What is the most important information I should know about CIBINQO?”**

The most common side effects of CIBINQO include:

See “What is the most important information I should know about CIBINQO.”

- | | |
|---|--|
| • common cold | • vomiting |
| • nausea | • mouth and throat pain |
| • headache | • flu |
| • herpes simplex including cold sores | • stomach flu |
| • increased blood level of creatinine phosphokinase | • bacterial skin infection (impetigo) |
| • dizziness | • high blood pressure |
| • urinary tract infection | • allergic skin rash to something you came into contact with |
| • tiredness | • stomach-area pain |
| • acne | • shingles |
| | • low platelet count |

CIBINQO may cause fertility problems in females, which may affect your ability to get pregnant. Talk to your healthcare provider if you have concerns about fertility.

Separation or tear to the lining of the back part of the eye (retinal detachment) has happened in people with atopic dermatitis treated with CIBINQO. Call your healthcare provider right away if you have any sudden changes in your vision during treatment with CIBINQO.

These are not all the possible side effects of CIBINQO.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

You may also report side effects to Pfizer at 1-800-438-1985.

How should I store CIBINQO?

- Store CIBINQO at room temperature between 68°F to 77°F (20°C to 25°C).
- Store CIBINQO in the original package.
- The container has a child resistant closure.

Keep CIBINQO and all medicines out of the reach of children.

General information about the safe and effective use of CIBINQO.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use CIBINQO for a condition for which it was not prescribed. Do not give CIBINQO to other people, even if they have the same symptoms you have. It may harm them.

You can ask your pharmacist or healthcare provider for information about CIBINQO that is written for health professionals.

What are the ingredients in CIBINQO?

Active ingredient: abrocitinib

Inactive ingredients: dibasic calcium phosphate anhydrous, hypromellose, iron oxide red, lactose monohydrate, Macrogol, magnesium stearate, microcrystalline cellulose, sodium starch glycolate, titanium dioxide, and triacetin.



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This Medication Guide has been approved by the U.S. Food and Drug Administration.

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