**abrocitinib**
Cibinqo

**Pharmaceutical company:** Pfizer, Inc.

**Pharmacologic classification:** Janus kinase (JAK) inhibitor

**Therapeutic classification:** Immunomodulator

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**AVAILABLE FORMS**
*Tablets:* 50 mg, 100 mg, and 200 mg

**INDICATIONS AND DOSAGES**
Refractory, moderate-to-severe atopic dermatitis not adequately controlled with other systemic drug products, including biologics, or when use of those therapies is inadvisable

**Adults:** 100 mg PO once daily. If inadequate response after 12 weeks, may increase to 200 mg once daily. Discontinue if there is an inadequate response after increasing to 200 mg once daily.

**Adjust-a-dose:** For patients with moderate renal impairment (eGFR 30 to 59 mL/min) or patients who are known or suspected CYP2C19 poor metabolizers, reduce dosage to 50 mg once daily; if inadequate response after 12 weeks, may double the dose. Refer to the manufacturer’s instructions for toxicity-related dosage adjustments.

**CONTRAINDICATIONS AND CAUTIONS**

- **Black Box Warning:** This drug may increase the risk of serious bacterial, fungal, viral, and opportunistic infections leading to hospitalization or death. The most frequently reported serious infections were herpes simplex, herpes zoster, and pneumonia. Avoid use in those with active, serious infection, including localized infections. Consider the risk and benefits of use in those with chronic or recurrent infection.

- Don’t give to patients with active tuberculosis (TB). Consider anti-TB treatment in patients with previously untreated latent TB, history of active TB if an adequate course of treatment can’t be confirmed, and in patients with a negative latent TB test but who have risk factors for TB infection.

- **Black Box Warning:** Patients age 50 and older with rheumatoid arthritis (RA) and at least one CV risk factor treated with a JAK inhibitor have an increased risk of major adverse CV events, including all-cause mortality. A higher rate of major adverse CV events (MACE) (CV death, MI, stroke) and thrombosis (pulmonary embolism, venous, arterial) have occurred with JAK inhibitors compared with TNF blockers in patients with RA. Patients who are current or past smokers are at additional risk. Discontinue the drug in patients who have MI, stroke, or symptoms of thrombosis. Abrocitinib isn’t approved for use in RA patients.

- **Black Box Warning:** Lymphoma and other malignancies have been observed in patients receiving JAK inhibitors used to treat inflammatory conditions. Patients with RA treated with JAK inhibitors have a higher rate of malignancies (excluding nonmelanoma skin cancer) compared with TNF blockers. Patients who are current or past smokers are at increased risk.

- **Black Box Warning:** Serious and sometimes fatal thrombosis, including deep vein thrombosis, pulmonary embolism, and arterial thrombosis, have occurred in patients treated with JAK inhibitors. Use cautiously in patients at increased risk for thrombosis after first carefully considering the risks and benefits.

- Use isn’t recommended for patients with active hepatitis B or hepatitis C.

- Avoid use in patients with severe (Child Pugh C) hepatic impairment.
Use cautiously in patients with moderate renal impairment.
Use not recommended in patients with severe renal impairment (eGFR 15 to 29 mL/min) or end-stage renal disease, platelet count less than 150,000/mm$^3$, absolute lymphocyte count less than 500/mm$^3$, ANC less than 1,000/mm$^3$ or hemoglobin less than 8 g/dL.
Use cautiously in older adults and patients who are CYP2C19 poor metabolizers.
Safety and effectiveness in children haven’t been determined.

Dialyzable drug: Unknown.

PREGNANCY-LACTATION-REPRODUCTION
- There are no adequate and well-controlled studies in pregnant women. Enroll women exposed to this drug during pregnancy in the pregnancy exposure registry at 1-877-311-3770.
- There are no data on the safety of breastfeeding. Advise against breastfeeding during treatment with abrocitinib and for one day after the last dose (approximately 5 to 6 elimination half-lives).
- This drug may impair female fertility.

INTERACTIONS
Drug-drug. Antiplatelet drugs (clopidogrel, prasugrel, ticagrelor [excluding low-dose aspirin]): May increase risk of bleeding with thrombocytopenia. Contraindicated during the first 3 months of treatment.
Moderate to strong CYP2C19 and CYP2C9 inhibitors (fluconazole): May increase abrocitinib levels. Avoid use with drugs that are moderate to strong inhibitors of both CYP2C19 and CYP2C9.
Other JAK inhibitors, biologic immunomodulators, or immunosuppressants: May enhance immunosuppressant effect. Avoid use together.
P-glycoprotein (P-gp) substrates (digoxin, dabigatran): May increase P-gp substrate levels and risk of adverse reactions of the substrate where small increases may lead to serious or life-threatening toxicities. Monitor closely or dose titrate P-gp substrate.
Strong CYP2C19 and CYP2C9 inducers (rifampin): May decrease abrocitinib levels. Avoid use together.
Strong CYP2C19 inhibitors (fluvoxamine): May increase abrocitinib levels. Reduce dosage of abrocitinib.
Vaccines: May diminish therapeutic effect of inactivated vaccines and increase risk of infection from live vaccines. Complete immunizations, including herpes zoster, following current guidelines prior to start of therapy. Avoid live vaccines immediately prior to, during, and immediately after therapy.
Drug-lifestyle. Smoking: Increased risk of malignancies and CV events. Discourage smoking.
Sun Exposure: Increased risk of malignancies. Limit exposure to sunlight and UV light.

ADVERSE REACTIONS
CNS: headache, dizziness, fatigue.
CV: hypertension.
EENT: nasopharyngitis, oropharyngeal pain.
GI: nausea, vomiting, gastroenteritis, upper abdominal pain, abdominal discomfort.
GU: UTI.
Hematologic: thrombocytopenia.
Metabolic: increased creatine kinase.
Skin: acne, impetigo, contact dermatitis.
Other: herpes simplex, herpes zoster, flulike symptoms, infections.
Reactions in bold italics are *life-threatening.*

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