

Drug Information Sheet("Kusuri-no-Shiori")

Internal
Revised: 04/2022

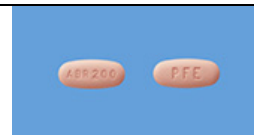
The information on this sheet is based on approvals granted by the Japanese regulatory authority. Approval details may vary by country. Medicines have adverse reactions (risks) as well as efficacies (benefits). It is important to minimize adverse reactions and maximize efficacy. To obtain a better therapeutic response, patients should understand their medication and cooperate with the treatment.

Brand name: CIBINQO Tablets 200mg

Active ingredient: Abrocitinib

Dosage form: pale red oval tablet, major axis: 18.4 mm, minor axis: 8.0 mm, thickness: 5.0 mm

Print on wrapping: CIBINQO, 200mg, サイバインコ錠, サイバインコ, PFE ABR 200



Effects of this medicine

This medicine inhibits enzymes called Janus Kinases (JAK) to suppress the action of multiple cytokines considered to be relating to atopic dermatitis and improves inflammation and itch.

It is usually used to treat atopic dermatitis with inadequate response to existing therapies. However, it does not completely cure the disease.

The following patients may need to be careful when using this medicine. Be sure to tell your doctor and pharmacist.

- If you have previously experienced any allergic reactions (itch, rash, etc.) to any medicines or foods.
If you have: infection (sepsis, etc.), active tuberculosis, liver dysfunction, decreased neutrophils, decreased lymphocytes, decreased hemoglobin level, decreased platelets, hepatitis B or its history, a risk of venous thromboembolism, a history of interstitial pneumonia, intestinal diverticulum or renal dysfunction.
- If you are pregnant, possibly pregnant or breastfeeding.
- If you are taking any other medicinal products. (Some medicines may interact to enhance or diminish medicinal effects. Beware of over-the-counter medicines and dietary supplements as well as other prescription medicines.)

Dosing schedule (How to take this medicine)

- Your dosing schedule prescribed by your doctor is((to be written by a healthcare professional))
- In general, for adults and children 12 years or over, take 100 mg of the active ingredient at a time, once a day. The dosage may be increased to 1 tablet (200 mg) at a time, once a day, according to the condition. Patients with moderate and severe renal dysfunction should take 50 mg at a time, once a day. Patients with moderate renal dysfunction should take 100 mg at a time, once a day, according to the condition. This preparation contains 200 mg of the active ingredient in a tablet. Strictly follow the instructions.
- If you miss a dose, take it as soon as you remember. However, if there is less than 12 hours before your next dose, skip the missed dose and follow your regular dosing schedule. You should never take two doses at one time.
- If you accidentally take more than your prescribed dose, consult with your doctor or pharmacist.
- Do not stop taking this medicine unless your doctor instructs you to do so.

Precautions while taking this medicine

- This medicine may make you susceptible to infections. Try to adopt preventive measures against infections, such as avoiding crowded spaces and washing hands and gargling the throat after going out.
- You should regularly undergo chest X-ray test and examinations to detect abnormalities in blood cell counts (white blood cell count, etc.) or lipid while you are using this medicine.
- You should continuously use topical moisturizer even while you are using this medicine.
- If you are a woman who is capable of pregnancy, avoid pregnancy while you are using this medicine and for a certain period after you discontinue this medicine.

Possible adverse reactions to this medicine

The most commonly reported adverse reactions include nausea, dizziness, headache, nasopharyngitis, acne and folliculitis. If any of these symptoms occur, consult with your doctor or pharmacist.

The symptoms described below are rarely seen as initial symptoms of the adverse reactions indicated in brackets. If any of these symptoms occur, stop taking this medicine and see your doctor immediately.

- cold-like symptoms, dull, small blisters appearing along a belt-like stretch of skin [infection]
- localized pain, red rash, edema [venous thromboembolism]
- nose bleeding, gum bleeding, dull, headache, fever, sore throat [decreased platelets, decreased hemoglobin, decreased lymphocytes, decreased neutrophils]
- fever, dry cough, breathing difficulty [interstitial pneumonia]
- general malaise, loss of appetite, nausea [liver dysfunction]

- nausea, vomiting, severe abdominal pain [gastrointestinal perforation]

The above symptoms do not describe all the adverse reactions to this medicine. Consult with your doctor or pharmacist if you notice any symptoms of concern other than those listed above.

Storage conditions and other information

- Keep out of reach of children. Store at room temperature (1 to 30 degrees Celsius), away from direct sunlight and moisture.
- Discard the remainder. Do not store them. Please consult with your pharmacy or medical institution, since proper disposal of the unused medicines requires attention. Do not give the unused medicines to others.
- Do not receive live vaccinations [for measles, rubella, mumps, chickenpox, BCG and polio] immediately before and while taking this medicine. Please consult with your doctor when you need to receive a vaccination.

For healthcare professional use only / /

For further information, talk to your doctor or pharmacist.