

CIBINQO™ FILM-COATED TABLET

Abrocitinib (50 mg, 100 mg, 200 mg)

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What Cibinqo is used for

Cibinqo is used in the treatment of patients 12 years of age and older with moderate to severe atopic dermatitis (red and itchy skin), including the relief of pruritus, who have had an inadequate response to prescribed topical therapy or for whom these treatments are not advisable.

Cibinqo can be used with or without medicated topical therapies for atopic dermatitis.

How Cibinqo works

Cibinqo is a Janus kinase (JAK) 1 inhibitor. The relevance of inhibition of specific JAK enzymes to therapeutic effectiveness is not currently known.

Before you use Cibinqo

When you must not use it

Pregnancy and lactation

Do not take Cibinqo if you are pregnant, trying to get pregnant or think you may be pregnant. The effect of abrocitinib has not been evaluated during pregnancy in humans.

If you are a woman of childbearing potential, you should use an effective method of contraception during treatment with Cibinqo, and for at least one month after your last treatment dose. Your doctor can advise you on suitable methods of

contraception.

Do not take abrocitinib if you are breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine.

- Before you start to use it

Take special care with Cibinqo:

- if you have long term and repeated or history of serious infections
- if you have tuberculosis or you are resident or travelled from native of tuberculosis or fungal infection
- if there is a risk of viral reactivation
- if you are vaccinated, it is recommended that patients be brought up to date with all immunizations, including prophylactic herpes zoster vaccinations, in agreement with current immunization guidelines
- if you have blood clots (especially in deep veins of legs) or if you are at high risk of having blood clots.
- if you have cancers
- if you have abnormal blood values
- if you have increased lipid levels.
- if you have immunosuppressive conditions or using immunosuppressive, e.g., biologic immunomodulators, potent immunosuppressants such as ciclosporin or other Janus kinase (JAK) inhibitors

- Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

You must not take Cibinqo with the following medications:

- CYP2C19/CYP2C9 inhibitors,

such as fluvoxamine or fluconazole (used to treat fungal infections), clopidogrel (used to prevent blood clot formation)

- CYP2C19/CYP2C9 inducers such as rifampin (used to treat bacterial infections), apalutamide (used to treat certain types of prostate cancer), efavirenz (used for the treatment and prevention of HIV-1 infection), enzalutamide (used to treat certain types of prostate cancer), phenytoin (used to treat epilepsy), S-mephenytoin.
- OAT3 inhibitors, such as probenecid (used to treat redness and pain in the joints as well as excessive uric acid levels in the blood)
- stomach acid reflux (such as antacids, famotidine or omeprazole), as they may reduce the amount of Cibinqo in your blood)
- digoxin (used to treat atrial fibrillation) and dabigatran (used to decrease the risk of stroke and blood clots), as Cibinqo may increase their effects.
- Potent immunosuppressants such as Ciclosporin
- other Janus kinase inhibitors, such as tofacitinib.

How to use Cibinqo

- How much to use

The recommended starting dose is 100 mg or 200 mg once daily as prescribed by your doctor.

You will get a starting dose based on your need and medical history or medical condition, therefore you should always take this medicine exactly as your doctor has told you. Your doctor may increase or decrease your dose depending on how well the medicine is working.

The lowest effective dose for maintenance should be considered. If you have taken Cibinqo for

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24 weeks and still show no improvement, your doctor may decide to permanently stop the treatment.

It can be used with or without medicated topical therapies for atopic dermatitis.

If you have any abnormalities in blood parameters, the treatment with Cibinqo is not recommended.

If you have mild kidney disease, the dose will remain the same. If you have moderate kidney disease the dose should be 100 mg or 50 mg once daily. If you have severe kidney disease recommended starting dose is 50 mg and maximum daily dose is 100mg.

If you have mild or moderate liver disease, no dose adjustment is required. Use of Cibinqo in severe stage liver diseases has not been studied.

For the elderly: For patients ≥ 65 years of age, recommended starting dose is 100 mg once a day.

Use in children: Safety and efficacy of Cibinqo has not been studied in children under 12 years of age.

- When to use it

Use as directed by your doctor or pharmacist.

Cibinqo tablets may be taken together with food or on an empty stomach. It is suggested that you take it the same time every day. If you experience nausea while taking Cibinqo, taking with food may improve the condition.

Swallow the tablets whole with plenty of water. Do not crush, split, or chew Cibinqo.

- How long to use it

It is important to keep taking Cibinqo as prescribed unless your doctor tells you to stop your treatment.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

- If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

Take the missed dose as soon as you remember. If it is less than 12 hours before your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention. If you have taken too much of your medicine, it is recommended that you should be monitored for signs and symptoms of any side effects.

While you are using it

- Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking Cibinqo.

Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

Do not stop taking the medicine

unless advised by your doctor.

Do not take any new medicines without consulting your doctor or pharmacist.

Do not give Cibinqo to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Driving and using machines

You may feel dizzy after taking Cibinqo. If this should happen, do not drive or operate machinery.

Side effects

Like all medicines Cibinqo can cause side effects, although not everybody gets them. Visit your doctor or pharmacist immediately if you experience any of the following:

Very common side effects (occurs more than 1 out of 10 patients):

- nausea

Common side-effects (occurs more than 1 out of 100 to less than 1 out of every 10 patients):

- viral infections (caused by herpes simplex and herpes zoster)
- decreased level of platelets in the blood
- dizziness
- headache
- vomiting
- abdominal pain upper
- acne
- increased creatinine phosphokinase levels in the blood

Uncommon side-effects (occurs more than 1 out of 1000 to less than 1 out of every 100 patients):

- pneumonia
- decreased level of lymphocytes (a type of white blood cell)
- increase level of lipids in blood
- blockage in arteries of lungs and in deep veins.

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If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of Cibinqo

- Storage

Keep out of the reach and sight of children.

Store below 30°C.

Keep in original package.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What Cibinqo looks like

CIBINQO 50 mg film-coated tablets
Pink, oval tablet 11 mm long and 5 mm wide, debossed with “PFE” on one side and “ABR 50” on the other.

CIBINQO 100 mg film-coated tablets
Pink, round tablet 9 mm in diameter, debossed with “PFE” on one side and “ABR 100” on the other.

CIBINQO 200 mg film-coated tablets
Pink, oval tablet 18 mm long and 8 mm wide debossed with “PFE” on one side and “ABR 200” on the other.

Cibinqo 50 mg, 100 mg and 200 mg film-coated tablet are available in High-density polyethylene (HDPE) bottles and polypropylene closure containing 14 or 30 film-coated tablets.

Polyvinylidene chloride (PVDC) blister with aluminium foil lidding film containing 7 film-coated tablets. Each pack contains 14, 28 or 91 film-coated tablets.

* Some product strengths or pack sizes may not be available in your country.

- Ingredients

- Active ingredient:
The active substance of Cibinqo film-coated tablets is abrocitinib.

- Inactive ingredients:
Microcrystalline cellulose
Dibasic calcium phosphate anhydrous
Sodium starch glycolate
Magnesium stearate

Film coat

Hypromellose (E464)
Titanium dioxide (E171)
Lactose monohydrate
Macrogol
Triacetin (E1518)
Iron red oxide (E172)

- MAL numbers

Cibinqo 50 mg tablets
MAL24066001AZ

Cibinqo 100 mg tablets
MAL24066002AZ

Cibinqo 200 mg tablets
MAL24066003AZ

Manufacturer

Pfizer Manufacturing Deutschland GmbH
Mooswaldallee 1

79108 Freiburg, Im Breisgau
Germany

Product Registration Holder

Pfizer (Malaysia) Sdn. Bhd.
Level 10 & 11,
Wisma Averis, Tower 2,
Avenue 5, Bangsar South,
No. 8 Jalan Kerinchi,
59200 Kuala Lumpur, Malaysia

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