

Package leaflet: Information for the patient

Cibinqo 50 mg film-coated tablets
Cibinqo 100 mg film-coated tablets
Cibinqo 200 mg film-coated tablets
abrocitinib

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

In addition to this leaflet, your doctor will also give you a patient card, which contains important safety information that you need to be aware of. Keep this patient card with you.

What is in this leaflet

1. What Cibinqo is and what it is used for
2. What you need to know before you take Cibinqo
3. How to take Cibinqo
4. Possible side effects
5. How to store Cibinqo
6. Contents of the pack and other information

1. What Cibinqo is and what it is used for

Cibinqo contains the active substance abrocitinib. It belongs to a group of medicines called Janus kinase inhibitors and works by reducing the activity of an enzyme in the body called 'Janus kinase', which is involved in inflammation. By reducing the activity of this enzyme, it helps to improve the condition of your skin and reduce itching. In addition, it can help improve your sleep disturbance (due to itch) and overall quality of life. It has also been shown to improve symptoms of anxiety and depression associated with atopic dermatitis.

Cibinqo is used to treat adults and adolescents 12 years of age and older with moderate-to-severe atopic dermatitis, also known as atopic eczema.

2. What you need to know before you take Cibinqo

Do not take Cibinqo

- if you are allergic to abrocitinib or any of the other ingredients of this medicine (listed in section 6).
- if you have a serious infection, including tuberculosis.
- if you have severe liver problems.
- if you are pregnant or breast-feeding (see section on Pregnancy, contraception and breast-feeding).

Warnings and precautions

Talk to your doctor or pharmacist before taking Cibinqo:

- if you have an infection or if you often get infections. Tell your doctor if you get symptoms such as fever, wounds, feeling more tired than usual or dental problems as these can be signs of infection. Cibinqo can reduce your body's ability to fight infections and may make an existing infection worse or increase the chance of you getting a new infection. If you have diabetes or are aged 65 years or older you may have an increased chance of getting infections.
- if you have, or have previously had, tuberculosis or have been in close contact with someone with tuberculosis. Your doctor will test you for tuberculosis before starting Cibinqo and may retest during treatment.
- if you have had a herpes infection (shingles), because Cibinqo may allow it to come back. Tell your doctor if you get a painful skin rash with blisters as these can be signs of shingles.
- you have had a rapidly spreading painful rash, blisters or sores (with or without fever) known as eczema herpeticum or Kaposi's varicelliform eruption.
- if you have ever had hepatitis B or hepatitis C.
- if you have recently had or plan to have a vaccination (immunisation) - this is because live vaccines are not recommended while using Cibinqo.
- if you have previously had blood clots in the veins of your legs (deep vein thrombosis) or lungs (pulmonary embolism) or have an increased risk for developing this (for example: if you had recent major surgery, if you use hormonal contraceptives\hormonal replacement therapy, if a coagulation defect is identified in you or your close relatives). Your doctor will discuss with you if Cibinqo is appropriate for you. Tell your doctor if you get sudden shortness of breath or difficulty breathing, chest pain or pain in upper back, swelling of the leg or arm, leg pain or tenderness, or redness or discoloration in the leg or arm as these can be signs of blood clots in the veins.
- if you have, or had heart problems because your doctor will discuss with you if Cibinqo is appropriate for you.
- if you have or have had cancer, smoke or have smoked in the past, because your doctor will discuss with you if Cibinqo is appropriate for you.
- Non-melanoma skin cancer has been observed in patients taking Cibinqo. Your doctor may recommend that you have regular skin examinations while taking Cibinqo. If new skin lesions appear during or after therapy or if existing lesions change appearance, tell your doctor.

Additional monitoring tests

You may need blood tests before you start taking Cibinqo, or while you are taking it, to check if you have low white blood cell count, low platelet count, or high blood fat (cholesterol) to ensure that treatment is not causing problems.

Children

Do not give this medicine to children below the age of 12 years because the safety and benefits of Cibinqo are not yet known in this group.

Other medicines and Cibinqo

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Your doctor might change the dose or tell you to stop taking Cibinqo if you are taking some of these other medicines:

- medicines to treat fungal infections (such as fluconazole), depression (such as fluoxetine, fluvoxamine), stroke (such as ticlopidine), as they may increase the side effects of Cibinqo.
- medicines to treat tuberculosis (such as rifampicin), seizures or fits (such as phenytoin), prostate cancer (such as apalutamide, enzalutamide), control HIV infection (such as efavirenz), as they may reduce how well Cibinqo works.
- medicines to treat depression (such as selegiline, isocarboxazid) as Cibinqo may increase their side effects.
- medicines to treat heart failure (such as digoxin), stroke (such as dabigatran) or atopic dermatitis (such as ciclosporin), as Cibinqo may increase their side effects.
- medicines to treat seizures (such as S-mephenytoin), as Cibinqo may increase its effects.
- medicines to treat stroke (such as clopidogrel), as Cibinqo may decrease its effects.

If any of the above apply to you or you are not sure, talk to your doctor or pharmacist before taking Cibinqo.

Pregnancy, contraception and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Pregnancy

Contraception in women

If you are a woman of childbearing potential, you should use an effective method of contraception to avoid becoming pregnant during treatment with Cibinqo and for at least 1 month after your last treatment dose. You must tell your doctor if you become pregnant as this medicine should not be used during pregnancy.

Breast-feeding

Do not use Cibinqo while breast-feeding as it is not known if this medicine passes into milk. You and your doctor should decide if you will breast-feed or use this medicine.

Driving and using machines

Cibinqo does not make you drowsy. However, if you experience dizziness after the intake of abrocitinib, you should refrain from driving or using machines until the dizziness resolves.

Cibinqo contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

Cibinqo contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

Elderly

Patients aged 65 years and older may be at increased risk of infections, heart attack and some types of cancer. Your doctor may decide that Cibinqo is not suitable for you.

3. How to take Cibinqo

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The recommended starting dose is 100 mg or 200 mg once a day as prescribed by your doctor. Your doctor may increase or decrease your dose depending on how well the medicine is working. Some patients need a lower starting dose and your doctor may give you 100 mg once a day if you are over 65 years old, if you are an adolescent (12 to 17 years old), or if you have certain medical history or medical condition. If you have kidney problems considered moderate-to-severe by your doctor, or if you are prescribed certain other medicines (see section 2), the dose of Cibinqo will be 50 mg or 100 mg once a day. If you have severe kidney problems, the starting dose of Cibinqo will be 50 mg once a day. 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.

After starting treatment, your doctor can adjust the dose based on how well the medicine works and any side effect you get. If the medicine is working well, the dose may be reduced. Your doctor may also stop treatment temporarily or permanently if blood tests show low white blood cell or platelet counts.

Cibinqo may be used with eczema medicines that you apply to the skin or it may be used on its own.

If you have taken Cibinqo for 12 weeks and show some response, continuation of treatment for a longer time may allow additional improvement. If there is no improvement after the first 12 weeks, your doctor may decide to permanently stop the treatment.

Cibinqo is for oral use. You should swallow your tablet whole with water. Do not split, crush or chew the tablet before swallowing as it may change how much medicine gets into your body.

You can take the tablets either with or without food. If you feel nausea when taking this medicine, taking with food may help. To help you remember to take your medicine, you may find it easier to take it at the same time every day.

If you take more Cibinqo than you should

If you take more Cibinqo than you should, contact your doctor. You may get some of the side effects described in section 4.

If you forget to take Cibinqo

- If you miss a dose, take it as soon as you remember.
- If you forget your dose, and there is less than 12 hours before your next dose, just skip the missed dose and take only a single dose as usual the following day.
- Do not take a double dose to make up for a forgotten tablet.

If you stop taking Cibinqo

You should not stop taking Cibinqo without discussing this with your doctor.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Some may be serious and need medical attention.

Serious side effects

Serious side effects are uncommon (may affect up to 1 in 100 people).

Talk to your doctor or get medical help straight away if you get any signs of:

- Shingles (herpes zoster), a painful skin rash with blisters and fever
- A rapidly spreading painful rash, blisters or sores (with or without fever) known as eczema herpeticum or Kaposi's varicelliform eruption
- Blood clots in the lungs, legs or pelvis with symptoms such as a painful swollen leg, chest pain or shortness of breath

Other side effects

Very common (may affect more than 1 in 10 people)

- Feeling sick in the stomach (nausea)

Common (may affect up to 1 in 10 people)

- Cold sores (herpes simplex)
- Vomiting
- Upper abdominal pain
- Headache
- Dizziness
- Acne
- Increase in an enzyme called creatine phosphokinase, shown by blood test

Uncommon (may affect up to 1 in 100 people)

- Pneumonia
- Low platelet count shown by blood test (see section 2 Warnings and precautions)
- Low white blood cell count shown by blood test (see section 2 Warnings and precautions)
- High blood fat (cholesterol) shown by blood test (see section 2 Warnings and precautions)

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Cibinqo

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month.

This product does not have any special storage restrictions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Cibinqo contains

- The active substance is abrocitinib.
Each 50 mg tablet contains 50 mg of abrocitinib.
Each 100 mg tablet contains 100 mg of abrocitinib.
Each 200 mg tablet contains 200 mg of abrocitinib.
- The other ingredients are:
Tablet core: microcrystalline cellulose (E460i), calcium hydrogen phosphate anhydrous (E341ii), sodium starch glycolate, magnesium stearate (E470b) (see section 2 Cibinqo contains sodium).
Film-coat: hypromellose (E464), titanium dioxide (E171), lactose monohydrate, macrogol (E1521), triacetin (E1518), iron red oxide (E172) (see section 2 Cibinqo contains lactose).

What Cibinqo looks like and contents of the pack

Cibinqo 50 mg film-coated tablets are pink, approximately 11 mm long and 5 mm wide oval tablets with “PFE” on one side and “ABR 50” on the other.

Cibinqo 100 mg film-coated tablets are pink, approximately 9 mm in diameter round tablets with “PFE” on one side and “ABR 100” on the other.

Cibinqo 200 mg film-coated tablets are pink, approximately 18 mm long and 8 mm wide oval tablets with “PFE” on one side and “ABR 200” on the other.

Cibinqo 50 mg film-coated tablets

The tablets are provided in blisters or bottles. Each blister pack contains 14, 28 or 91 tablets. Each bottle contains 14 or 30 tablets.

Cibinqo 100 mg film-coated tablets

The tablets are provided in blisters or bottles. Each blister pack contains 14, 28 or 91 tablets. Each bottle contains 14 or 30 tablets.

Cibinqo 200 mg film-coated tablets

The tablets are provided in blisters or bottles. Each blister pack contains 14, 28 or 91 tablets. Each bottle contains 14 or 30 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

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