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 (fever, sweating, or chills, muscle aches, cough or shortness of breath, blood in your phlegm, weight loss, diarrhoea or stomach pain, burning when you urinate or urinating more often than usual, feeling very tired) – Cibinqo can reduce your body’s ability to fight infections and so may worsen an infection that you already have, or make it more likely for you to get a new infection.
- 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 had blood clots in the veins of your legs (deep vein thrombosis) or lungs (pulmonary embolism). Tell your doctor if you get a painful swollen leg, chest pain, or shortness of breath as these can be signs of blood clots in the veins.
- if you have cancer or have had any cancer - because your doctor will have to decide if you can still be given Cibinqo.

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.

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.

**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’.

### 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 for most patients is 200 mg once a day. Your doctor may give you the lower starting dose of 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 conditions. The maximal dose is 200 mg once daily.

After starting treatment, your doctor may decrease the dose to 100 mg once a day, or increase to 200 mg once a day based on how you respond or how you tolerate the medicine.

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

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. Your doctor may also stop treatment temporarily or permanently if blood tests show low white blood cell or platelet counts.

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](http://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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Manufacturer

Pfizer Manufacturing Deutschland GmbH
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For any information about this medicine, please contact:
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