

Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986

This medicine is dispensed with a doctor's prescription only

Cibinqo® 50 mg, film-coated tablets

Cibinqo® 100 mg, film-coated tablets

Cibinqo® 200 mg, film-coated tablets

Active ingredient

Cibinqo 50 mg: Each tablet contains abrocitinib 50 mg

Cibinqo 100 mg: Each tablet contains abrocitinib 100 mg

Cibinqo 200 mg: Each tablet contains abrocitinib 200 mg

For a list of inactive ingredients and allergens in this medicine: see section 2 under "Important information about some of this medicine's ingredients" and section 6 "Further information".

Read the entire leaflet carefully before using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.

This medicine has been prescribed to treat your illness. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar to yours.

This medicine is intended for adults above the age of 18 years.

1. WHAT IS THIS MEDICINE INTENDED FOR?

Cibinqo is indicated for the treatment of moderate-to-severe atopic dermatitis in adults who are candidates for systemic therapy.

Therapeutic group: A medicine from the class of Janus kinase (JAK) inhibitors.

2. BEFORE USING THIS MEDICINE

Do not use this medicine if:

- You are sensitive (allergic) to abrocitinib or to any of the other ingredients in this medicine (see section 6)
- You have a severe infection, including tuberculosis
- You have severe liver problems
- You are pregnant or breastfeeding (see the "Pregnancy, contraception, breastfeeding and fertility" section)

Special warnings regarding use of the medicine

Before treatment with Cibinqo, tell your doctor if:

- You have an infection (shown by signs such as fever, sweating or chills, muscle aches, cough or shortness of breath, blood in phlegm, weight loss, diarrhoea or abdominal pain, burning upon urination or urinating more often than usual, feeling very tired) – Cibinqo may reduce your body's ability to fight infections, thereby worsening an existing infection or making it more likely for you to get a new infection.
- You have or have had tuberculosis, or have been in close contact with someone with tuberculosis. Your doctor will refer you for tuberculosis diagnosis before treatment with Cibinqo and possibly during the treatment as well.

- You have had herpes zoster (shingles), because Cibinqo may cause a relapse. Tell your doctor if you get a painful skin rash with blisters, as this may be a sign of shingles.
- You have had hepatitis B or hepatitis C.
- You have recently received or plan to receive a vaccine – since it is recommended to avoid certain vaccine types (live vaccines) immediately before and during treatment with Cibinqo.
- You have had blood clots in the leg veins (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 may be signs of blood clots in the veins.
- You have high blood cholesterol levels or other medical conditions that make you more likely to develop a heart disease – it is not clear if Cibinqo increases the risk of heart disease, and your doctor will discuss with you whether this treatment is appropriate for you or whether you need additional tests during treatment with this medicine.
- You have or have had cancer – it is not clear if Cibinqo increases the risk of cancer, and your doctor will discuss with you whether this treatment is appropriate for you and whether check-ups will be necessary during treatment.

Children and adolescents

This medicine is not indicated for children and adolescents below the age of 18 years. There is no information regarding the safety and effectiveness of using this medicine in children and adolescents below the age of 18 years.

Tests and follow-up

Your doctor will refer you for blood tests before and during Cibinqo treatment and will adjust your treatment as necessary.

Drug interactions

If you are taking or have recently taken other medicines, including nonprescription medicines and dietary supplements, tell your doctor or pharmacist. Particularly if you are taking medicines for treating:

- fungal infections (such as fluconazole), depression (such as fluoxetine or fluvoxamine), stroke (such as ticlopidine), as they may increase the side effects of Cibinqo.
- stomach acid reflux (such as antacids, famotidine or omeprazole), as they may reduce the amount of Cibinqo in your blood.
- depression (such as citalopram, clobazam or escitalopram), as Cibinqo may increase their effects.
- neurofibromatosis type I (such as selumetinib), as Cibinqo may increase their effects.
- heart failure (such as digoxin) or stroke (such as dabigatran), as Cibinqo may increase their effects.
- seizures (such as S-mephenytoin), as Cibinqo may increase their effects.
- stroke (such as clopidogrel), as Cibinqo may decrease their effects.
- asthma, atopic dermatitis or rheumatoid arthritis (such as biologic antibody therapies, medicines that control the immune response such as ciclosporin, other Janus kinase inhibitors, such as baricitinib, upadacitinib), as they may increase the risk of side effects.

Your doctor can tell you to avoid or stop taking Cibinqo if you are taking medicines to treat:

- tuberculosis (such as rifampicin), seizures or fits (such as phenytoin), prostate cancer (such as apalutamide, enzalutamide), or HIV infection (such as efavirenz), as these may reduce the efficacy of Cibinqo.

If any of the above applies to you or if you are not sure, talk to your doctor or pharmacist.

Using this medicine and food

You can take the medicine with or without food. If you experience nausea when taking this medicine, it may help to take it with food.

Pregnancy, contraception, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to become pregnant, consult your doctor before taking this medicine.

Contraception in women

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. Your doctor can advise you on suitable methods of contraception.

Pregnancy

Do not use Cibinqo if you are pregnant, think you may be pregnant or are planning to become pregnant, since the medicine may harm the developing baby. Tell your doctor right away if you become pregnant or think you might have become pregnant during treatment.

Breastfeeding

Do not use Cibinqo if you are breastfeeding as it is not known if this medicine passes into breast milk and affects the baby. You and your doctor should decide if you will breastfeed or take this medicine.

Fertility

Cibinqo may cause a temporary reduction in fertility in women of childbearing potential. This effect is reversible after stopping treatment.

Driving and using machines

Cibinqo has no or negligible effect on the ability to drive or use machines.

Important information about some of this medicine's ingredients

Cibinqo contains lactose monohydrate and sodium

If you have been told by your doctor that you have intolerance to certain sugars, contact your doctor before starting treatment with this medicine.

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

3. HOW TO USE THIS MEDICINE?

Always use this medicine according to your doctor's instructions.

Check with the doctor or pharmacist if you are uncertain about the dosage and treatment regimen of the medicine.

The dosage and treatment regimen will be determined by your doctor only.

Cibinqo tablet is taken by mouth. It may be used alone or with other topical medicines (by application on the skin) for dermatitis (eczema).

The recommended starting dose is 200 mg once a day. Some patients need a lower starting dose and your doctor may give you a starting dose of 100 mg once a day if you are over 65 years of age, if you are at increased risk of deep vein thrombosis/pulmonary embolism or if you have a certain medical history or medical condition. If you have moderate-to-severe kidney dysfunction, or if you are taking certain other medicines, the starting dose can be either 50 mg or 100 mg once a day. You will get a starting dose based on your medical needs and medical history, and therefore you should always take this medicine according to your doctor's instructions.

The maximum daily dose is 200 mg.

After starting treatment, your doctor may adjust the dosage based on how well the medicine works for you and any side effects you get. If the medicine is working well for you, the dose may be reduced. The treatment may need to be stopped temporarily or permanently if blood tests show low white blood cell or platelet counts.

If you have taken Cibinqo for 24 weeks and there is still no improvement in your condition, your doctor may decide to stop the treatment.

Do not exceed the recommended dose.

Swallow the medicine whole with water. Do not split, crush or chew the tablet before swallowing as it may change the amount of medicine that enters your body.

You can take the medicine with or without food. If you experience nausea when taking this medicine, it may help to take it with food. To avoid forgetting to take the medicine, it is recommended to take it at the same time every day.

If you have taken an overdose, or if a child has accidentally swallowed some medicine, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you. You may experience some of the side effects described in section 4.

If you forget to take the medicine at the scheduled time

- If you miss a dose, take it as soon as you remember, unless your next dose is due in less than 12 hours.
- If there is less than 12 hours before your next dose, skip the missed dose and take your next dose at the usual time.
- Do not take a double dose to make up for a missed dose.

If you stop taking Cibinqo

Even if your health improves, do not stop treatment with this medicine without consulting your doctor or pharmacist.

Adhere to the treatment as recommended by your doctor.

Do not take medicines in the dark! Check the label and dose each time you take medicine. Wear glasses if you need them.

If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Cibinqo may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.

Serious side effects

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

- Shingles (herpes zoster), a painful skin rash with blisters and fever
- Blood clots in the lungs, legs or pelvis with symptoms such as a painful swollen leg, chest pain or shortness of breath

Additional side effects

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

- Feeling sick (Nausea)

Common side effects (may affect up to 1 in 10 people):

- Cold sores and other types of herpes simplex infections
- Vomiting
- Abdominal pain
- Headache
- Dizziness
- Acne
- Increase in the levels of creatine phosphokinase enzyme in blood tests

Uncommon side effects (may affect up to 1 in 100 people):

- Pneumonia
- Low platelet count in blood tests
- Low white blood cell count in blood tests
- Elevated blood fat (cholesterol) level in blood tests (see section 2 "Special warnings regarding use of the medicine")

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects or by using the link: <https://sideeffects.health.gov.il>.

5. HOW TO STORE THE MEDICINE?

- Prevent poisoning! This and any other medicine should be kept in a closed place, out of the reach and sight of children and/or infants to prevent poisoning. Do not induce vomiting unless explicitly instructed to do so by a doctor.
- Do not use the medicine after the expiry date (exp. date) which is stated on the package. The expiry date refers to the last day of that month.

Storage conditions

- There are no special storage conditions. It is recommended to store at room temperature.
- Shelf life after first opening for the bottle pack: 45 days.

6. FURTHER INFORMATION

In addition to the active ingredient, this medicine also contains:

microcrystalline cellulose, dibasic calcium phosphate anhydrous, sodium starch glycolate, magnesium stearate, hypromellose, titanium dioxide, lactose monohydrate, macrogol, triacetin, iron oxide red

What the medicine looks like and contents of the pack:

Cibinqo 50 mg:

A pink oval tablet, imprinted with "ABR 50" on one side and "PFE" on the other.

The medicine is marketed in a bottle pack containing 14 or 30 tablets, or in a blister pack containing 14, 28 or 91 tablets.

Cibinqo 100 mg:

A pink round tablet, imprinted with "ABR 100" on one side and "PFE" on the other.

The medicine is marketed in a bottle pack containing 14 or 30 tablets, or in a blister pack containing 14, 28 or 91 tablets.

Cibinqo 200 mg:

A pink oval tablet, imprinted with "ABR 200" on one side and "PFE" on the other.

The medicine is marketed in a bottle pack containing 14 or 30 tablets, or in a blister pack containing 14, 28 or 91 tablets.

Not all pack sizes may be marketed.

Registration holder and address: Pfizer Pharmaceuticals Israel Ltd., 9 Shenkar St., Herzliya Pituach 46725.

Registration number of the medicine in the Ministry of Health's National Drug Registry:

Cibinqo 50 mg: 171-30-37238

Cibinqo 100 mg: 171-31-37239

Cibinqo 200 mg: 171-32-37240

Approved by the Ministry of Health in 01/2023