

Vaccines

Talk to your doctor or pharmacist if you have recently had or plan to have a vaccination (immunisation) - this is because certain live vaccines (e.g., Zostavax®) are not recommended immediately before and while using Cibirqo.

Risk of blood clots in veins or lungs:

Talk to your doctor or pharmacist 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.

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Risk of heart disease:

Talk to your doctor or pharmacist before and during the treatment if you:

- develop severe chest pain or tightness (that may spread to arms, jaw, neck and back), shortness of breath, cold sweat, light headedness or sudden dizziness, as these may be signs of a heart attack.

Risk of cancer:

Non-melanoma skin cancer has been observed in patients taking Cibirqo. Your doctor may recommend that you have regular skin examinations while taking Cibirqo. If new skin lesions appear during or after therapy or if existing lesions change appearance, tell your doctor.

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Laboratory tests

Your doctor will ask you to get laboratory tests (including testing for high cholesterol) before starting Cibirqo and while you are taking Cibirqo and may adjust your treatment accordingly. You should not receive Cibirqo if your lymphocyte, neutrophil, haemoglobin or platelet count is too low.

Contraception and pregnancy

Cibirqo must NOT be used during pregnancy nor during breastfeeding. If you are a woman of childbearing potential, you should use an effective method of contraception during treatment with Cibirqo and for at least one month after your last dose of Cibirqo. Talk to your doctor about suitable methods of contraception.

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Tell your doctor straight away if you become pregnant or think you might have become pregnant during treatment.

REPORTING OF SUSPECTED ADVERSE REACTIONS

Adverse events can be reported directly to the Ministry of Health using the adverse events reporting portal which is available on the home page of the Ministry of Health website:

www.health.gov.il

or by this link:

<https://sideeffects.health.gov.il>

Side effects can also be reported to Pfizer by email:

isr.aereporting@pfizer.com

This card was approved according to the guidelines of the Ministry of Health on August 2024.

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Patient Safety Information Card

CIBINQO 50 mg, 100 mg, 200 mg (Abrocitinib)



The Bearer of this card is treated with Cibinqo

Patient's Name:

Date of Birth:

Doctor's name
(who prescribed Cibinqo):

Doctor's phone number:

Cibinqo treatment start date:

Dosage:

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Safety Information for Patients about Cibinqo:

- This card contains important safety information you should be aware of before and during treatment with Cibinqo.
- For more information read the patient information leaflet included in each pack of Cibinqo.
- Ask your doctor or pharmacist if any of the information is not clear.

Keep this card with you and show to any healthcare professional involved in your medical care – for example, your pharmacist, or an emergency doctor. Keep this card with you for at least 2 months after taking the last dose of Cibinqo.

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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, which help to reduce inflammation. It works by reducing the activity of an enzyme in the body called 'Janus kinase', which is involved in inflammation.

Cibinqo is used to treat adults with moderate-to-severe atopic dermatitis, (also known as atopic eczema) who are candidates for systemic therapy. By reducing the activity of Janus kinase enzymes, Cibinqo lessens itching and inflammation of the skin. This in turn can reduce sleep disturbances and other consequences of atopic eczema

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such as anxiety or depression and improves overall quality of life.

How to take Cibinqo:

- 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 the efficacy of the medicine. 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 65 years of age or older, or if you have a certain medical history or medical condition. A reduced dose is also recommended to patients with kidney dysfunction.
- Your doctor may decide to stop Cibinqo if it does not work for you

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within 24 weeks.

- The dose of Cibinqo should be adjusted if you are prescribed certain other medicines. In addition, treatment should be permanently or temporarily discontinued if blood tests reveal low haemoglobin, white blood cell, or platelet counts.
- Notify your physician if you are taking or have recently taken other medications, including non-prescription medications and dietary supplements, if you have liver or kidney problems and regarding any changes in your medical condition.
- If you forget to take this medicine at the appropriate time: if you miss a dose, take it as soon as you

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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.

You should know about certain side effects and topics listed below, talk to your doctor if you get any side effects:

Risk of infections

Talk to your doctor or pharmacist before and during the treatment with Cibinqo if you:

- get symptoms such as fever, wounds, feeling more tired than usual or dental problems as these can be signs of infection.

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