

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.

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.

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Risk of cancer:

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

Laboratory tests

Your doctor will ask you to get laboratory tests (including testing for high cholesterol) before starting Cibirgo and while you are taking Cibirgo and may adjust your treatment accordingly.

You should not receive Cibirgo if your lymphocyte, neutrophil, haemoglobin or platelet count is too low.

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Contraception and pregnancy

Cibirgo 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 Cibirgo and for at least one month after your last dose of Cibirgo. Talk to your doctor about suitable methods of contraception.

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

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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 and its content have been approved by the Ministry of Health in February 2023

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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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- 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 200 mg once daily.
- A starting dose of 100 mg once daily is recommended for patients ≥ 65 years of age and in patients at high risk of developing blood clots in veins or lungs. A reduced dose is also recommended to patients with kidney problems.
- Your doctor may decide to stop Cibinqo if it does not work for you within 24 weeks.
- The dose of Cibinqo should be adjusted if you have kidney problems or if you are prescribed

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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, take the next dose at the usual time. Do not take a double dose.

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

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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.

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 Cibinqo.

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