

IMPORTANT SAFETY INFORMATION

Cibinqo (Abrocitinib) - PATIENT CARD

This document is approved by the Executive Directorate of Pharmacovigilance at SFDA

Your name:

Doctor's name (who prescribed Cibinqo):

Doctor's phone number:

The date you started Cibinqo:

Safety Information for Patients About Cibinqo:

- This card contains important safety information you should be aware of – before and during treatment.
- 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.

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

Risk of Infections:

Do not take Cibinqo if you have a serious infection ongoing, including tuberculosis.¹

Tell your doctor straight away 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.¹

Have ever 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 this can be a sign of shingles.¹

Have, or have previously had tuberculosis or have been in close contact with a person with tuberculosis.¹

Vaccines:

Talk to your doctor or pharmacist if you have recently had or plan to have a vaccination (immunisation) - this is because certain vaccines (live vaccines) are not recommended while using Cibinqo.¹

Blood clots in veins [known as Deep Vein Thrombosis or (DVT)] or lungs [known as Pulmonary Embolism (PE)]¹

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Tell your doctor if you have previously had blood clots in the veins of your legs (deep vein thrombosis) or lungs (pulmonary embolism). 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.¹

Laboratory Tests:

Your doctor will carry out blood tests before and during Cibinqo treatment and may adjust your treatment if necessary.¹

Contraception and Pregnancy:

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 dose. Your doctor can advise you on suitable methods of contraception.¹

Do not use Cibinqo if you are pregnant, think you may be pregnant or are planning to have a baby since it can harm the developing baby. Tell your doctor right away if you become pregnant or think you might have become pregnant during treatment.¹

Adverse Events Reporting:

Suspected adverse reactions should be reported to:

- The National Pharmacovigilance & Drug Safety Center (NPC) at Saudi Food and Drug Authority (SFDA)

SFDA Call Center: 19999

Toll Free Phone: 8002490000

Fax: +966-11-2057662

E-mail: npc.drug@sfd.a.gov.sa

Website: <http://ade.sfd.a.gov.sa/>

- Pharmacovigilance Department in the Company

E-mail: SAU.AEReporting@pfizer.com

For extra copies, please send an email with your contact details and the required amount to SAU.AEReporting@pfizer.com

SFDA: Saudi Food and Drug Authority; **DVT:** Deep Vein Thrombosis; **PE:** Pulmonary Embolism; **NPC:** National Pharmacovigilance Center

Reference:

1. CIBINQO® Patient Information Leaflet, Saudi Arabia, March 2024.