

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.

Tell your doctor straight away if you:

Develop symptoms of an infection such as, 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 than usual, feeling very tired.

Develop any symptoms of a herpes infection (shingles), such as painful skin rash with blisters.

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

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 measles, mumps, rubella, (MMR combined vaccine), Rotavirus, Smallpox, Chickenpox and Yellow fever. are not recommended immediately before and while using Cibinqo.

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



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Tell your doctor straight away if:

- you have had blood clots in the veins of your legs (DVT) or lungs (PE). If you develop shortness of breath, chest pain, painful swollen leg while taking Cibinqo, as these may be signs of blood clots in the veins.

Laboratory tests

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

Contraception and pregnancy

Cibinqo must NOT be used during 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 dose of Cibinqo. 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.

Adverse Events Reporting

Suspected adverse reactions should be reported to:

- The National Pharmacovigilance & Drug safety Centre (NPC) at Saudi Food and Drug Authority (SFDA)
SFDA Call Center: 19999
Toll Free Phone: 8002490000
Fax: +966-11-2057662
E-mail: npc.drug@sfda.gov.sa
Website: <http://ade.sfda.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