CIBINQO®
(abrocitinib) tablets 50mg 100mg 200mg

IMPORTANT SAFETY INFORMATION

Cibinqo (Abrocitinib) Prescriber Brochure

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

This Prescriber Brochure contains important safety information that you need to consider when prescribing and maintaining patients on Cibinqo therapy, namely:

- Thrombotic events including pulmonary embolism
- Potential risk of Infections (including herpes zoster and serious and opportunistic infections)
- Potential risk of malignancy
- Potential risk of Major Adverse Cardiovascular Events
- Embryofoetal toxicity following exposure in utero

Please read this brochure in full along with the prescribing information.

About Cibinqo

Cibinqo is a Janus kinase (JAK) 1 inhibitor.

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

Important points to remember - Patient Card

Prior to starting treatment with Cibinqo:

- Provide the Patient Card to patients and explain that the Patient Card contains important safety information that patients should be aware of before, during, and after treatment with Cibinqo.
- Discuss with patient important safety information with Cibinqo treatment mentioned at the start of this document and ensure patient understanding of this important safety information as well as ways to minimize this. Encourage patients asking questions about the Patient Card and safe use of Cibinqo.
- Advise patients about the importance of the Patient Card and to keep it with them and to have any doctor or pharmacist involved in their care review the Patient Card.
- Advise patients that they should read the Patient Card along with the Patient Information Leaflet.

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Thrombotic events including pulmonary embolism (PE):

Events of deep venous thrombosis (DVT) and PE have been reported in patients receiving Cibinqo. Cibinqo should be used with caution in patients at high risk for DVT or PE.

Before starting Cibinqo:

- The risks and benefits of Cibinqo treatment should be considered prior to initiating treatment. Risk factors that should be considered in determining the patient's risk for DVT/PE include older age, obesity, a medical history of DVT/PE, prothrombotic disorder, use of combined hormonal contraceptives or hormone replacement therapy, patients undergoing major surgery, or prolonged immobilization.

If clinical features of a DVT/PE occur:

- Cibinqo treatment should be discontinued, and patients should be evaluated promptly, followed by appropriate treatment.

Infections (including herpes zoster and serious and opportunistic infections):

Cibinqo must not be used in patients with active serious systemic infections, including tuberculosis (TB). The most frequent serious infections in clinical studies were herpes simplex, herpes zoster, and pneumonia.

Patients should be closely monitored for the development of signs and symptoms of infection, including viral reactivation, during and after treatment with Cibinqo.

It is important to tell patients to get immediate medical attention if they have symptoms suggesting infection. This is to ensure rapid evaluation and appropriate treatment.

Before starting Cibinqo:

- The risks and benefits of treatment should be carefully considered prior to initiating in patients:
  - with chronic or recurrent infection
  - who have been exposed to TB
  - with a history of a serious or an opportunistic infection
  - who have resided or travelled in areas of endemic TB or endemic mycoses; or
  - with underlying conditions that may predispose them to infection.

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- Patients should be screened for TB before starting treatment and yearly screening for patients in highly endemic areas for TB should be considered.
- Cibinqo should not be given to patients with active TB. For patients with a new diagnosis of latent TB or prior untreated latent TB, preventive therapy for latent TB should be started prior to initiation of Cibinqo.
- Patients should be screened for viral hepatitis before and during therapy with Cibinqo in accordance with clinical guidelines. If hepatitis B virus DNA is detected while receiving Cibinqo, a liver specialist should be consulted.
- Before and during treatment with Cibinqo, patients should be monitored using a complete blood count (including absolute lymphocyte count, absolute neutrophil count).

If a new infection develops during treatment with Cibinqo:

- Immediately carry out complete diagnostic testing and initiate appropriate antimicrobial therapy.
- Closely monitor the patient and Cibinqo therapy should be temporarily interrupted if the patient is not responding to standard therapy.

If a patient develops a serious infection, sepsis or opportunistic infection:

- Consider dose interruption of Cibinqo until the infection is controlled.

Vaccines:

No data are available on the response to vaccination in patients receiving Cibinqo. Before initiating treatment, it is recommended that patients be brought up to date with all immunizations, including prophylactic herpes zoster vaccinations, in agreement with current immunization guidelines.

Live vaccines measles, mumps, rubella, (MMR combined vaccine), Rotavirus, Smallpox, Chickenpox and Yellow fever. should be avoided during Cibinqo treatment, or just before starting Cibinqo treatment.

Malignancy:

Malignancies, including non-melanoma skin cancer (NMSC), have been observed in clinical studies with patients receiving Cibinqo.

Clinical data are insufficient to assess the potential relationship of exposure to Cibinqo and the development of malignancies. Long-term safety evaluations are ongoing.

Before starting Cibinqo:

- The risks and benefits of treatment should be considered prior to initiating in patients with a known malignancy other than a successfully treated NMSC or cervical cancer in situ or when considering continuing Cibinqo therapy in patients who develop a malignancy.

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- Periodic skin examination is recommended for patients who are at increased risk for skin cancer.

Major Adverse Cardiovascular Events (MACE):

Dose dependent increases in blood lipid parameters were reported in patients treated with Cibinqo.

Lipid parameters should be assessed prior to initiation, a ter 4 weeks of therapy and therea ter according to patient's risk for cardiovascular disease and clinical guidelines for hyperlipidaemia.

The effect of lipid parameter elevations on cardiovascular morbidity and mortality has not been determined. Patients with abnormal lipid parameters should be further monitored and managed according to clinical guidelines, due to the known cardiovascular risks associated with hyperlipidaemia.

In patients with a high burden of cardiovascular risk factors, the risks and benefits of abrocitinib compared to that of other available therapies for atopic dermatitis should be considered. If abrocitinib is chosen, interventions to manage lipid concentrations should be implemented according to local guidelines.

Embryofoetal toxicity following exposure in utero:

There are no or limited amount of data on the use of Cibinqo in pregnant women. Studies in animals have shown reproductive toxicity.

- Cibinqo is contraindicated during pregnancy.
- Women of reproductive potential should be advised to use effective contraception during and for 1 month following the final dose of Cibinqo. Pregnancy planning and prevention for females of reproductive potential should be encouraged.
- Advise patients to inform their healthcare provider immediately if they think they could be pregnant or if pregnancy is confirmed.

Further information:

- As a healthcare professional, it is important that you report any suspected adverse reactions 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/

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• 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 Quantities to SAU.AEReporting@pfizer.com

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