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

Prescriber Guide

Cibinqo▼ (abrocitinib)

This Prescriber Guide is an important risk minimisation measure and contains important safety information for prescribers. It aims to provide guidance on Cibinqo to the prescribing physicians with respect to therapeutic indications, dosing and administration including considerations for administration, instruction on monitoring laboratory parameters, precautions and warnings, patient counselling, reporting of adverse events, and a summary of the risk management plan.

The purpose of the Prescriber Guide is to inform healthcare professionals as to how they can minimize the important risks associated with Cibinqo. It is a mandatory condition of the marketing authorisation.

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

- Venous thrombotic events, including pulmonary embolism
- Risk of herpes zoster and potential risk of other infections including serious infections, opportunistic infections and eczema herpeticum
- Potential risk of malignancy
- Potential risk of Major Adverse Cardiovascular Events as a result of hyperlipidaemia
- Embryofoetal toxicity following exposure in utero
- Use in breast-feeding

Please read this Guide in full along with the prescribing information for Cibinqo.

About Cibinqo

Cibinqo is a Janus kinase (JAK) 1 inhibitor.
Cibinqo is indicated for the treatment of moderate-to-severe atopic dermatitis in adults and adolescents 12 years and older 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 it contains important safety information that patients should be aware of before, during, and after treatment with Cibinqo
- Discuss with the patient the 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 minimise risk. Encourage patients to ask questions about the Patient Card and safe use of Cibinqo
- Advise patients of 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

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. Eczema herpeticum was also observed in patients treated with Cibinqo.
Patients should be closely monitored for the development of signs and symptoms of infection 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 Cibinqo in patients:

- With chronic or recurrent infection
- Who have been exposed to TB
- Who have resided or travelled in areas of endemic TB or endemic mycoses
- With a history of a serious or an opportunistic infection
- With underlying conditions that may predispose them to infection

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 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.

Screen patients 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.

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 immunisations, including prophylactic herpes zoster vaccinations, in agreement with current immunisation guidelines.

Use of live, attenuated vaccines should be avoided during or immediately prior to Cibinqo therapy.

Venous thrombotic events (VTE) 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 Cibinqo. 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 immobilisation

If clinical features of a DVT/PE occur:

- Cibinqo treatment should be discontinued, and patients should be evaluated promptly, followed by appropriate 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
- Periodic skin examination is recommended for patients who are at increased risk for skin cancer

Major Adverse Cardiovascular Events (MACE) as a result of hyperlipidaemia:

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

Lipid parameters should be assessed prior to initiation, after 4 weeks of therapy and thereafter according to patients' 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.

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
- Advise patients to inform their healthcare provider immediately if they think they could be pregnant or if pregnancy is confirmed

Use in breast-feeding:

- There are no data on the presence of Cibinqo in human milk, the effects on the breastfed infant, or the effects on milk production
- Cibinqo was secreted in milk of lactating rats. A risk to newborns/ infants cannot be excluded and Cibinqo is contraindicated during breastfeeding

For more details on prescribing Cibinqo, please refer to the Summary of Product Characteristics

Further information:

All the educational materials including the patient alert card and the prescriber guide are available at: http://www.medicines.org.uk/emc/.

▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information.

Suspected Adverse Drug Reactions (side effects) or medication errors may be reported using the Medicines Authority ADR reporting form, which is available online at http://www.medicinesauthority.gov.mt/adrportal, and sent by post or email to; P: Pharmacovigilance Section at Post-Licensing Directorate, Medicines Authority, Sir Temi Żammit Buildings, Malta Life Sciences Park, San Ġwann SĠN 3000 E: postlicensing.medicinesauthority@gov.mt
Alternatively you may also report such events promptly to Pfizer at Pfizer Hellas S.A., 243 Messoghion Ave. N.Psychiko, Athens GR-15451, Greece. Pfizer Hellas Pharmacovigilance Department contact details: +30 210 67 85 908 and +30 210 67 85 808 (24hour line), fax: +30 210 81 99 096. Healthcare professionals should report adverse events or reactions by brand name and batch number.

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