EMA/700036/2021
EMEA/H/C/005452

Cibinqo (*abrocitinib*)

An overview of Cibinqo and why it is authorised in the EU

What is Cibinqo and what is it used for?

Cibinqo is a medicine for treating adults with moderate to severe atopic dermatitis (also known as eczema, when the skin is itchy, red and dry). It is used in patients for whom treatment applied directly to the skin cannot be used or is not sufficient.

Cibinqo contains the active substance abrocitinib.

How is Cibinqo used?

Cibinqo can only be obtained with a prescription and treatment should be started and monitored by a doctor experienced in the management of patients with atopic dermatitis.

The medicine is available as tablets and the recommended dose is 200 mg once a day. Your doctor may interrupt treatment if certain side effects occur, including serious infection. Your doctor may also stop treatment with Cibinqo if symptoms do not improve after 24 weeks of treatment.

For more information about using Cibinqo, see the package leaflet or contact your doctor or pharmacist.

How does Cibinqo work?

The active substance in Cibinqo, abrocitinib, works by blocking the action of enzymes known as Janus kinases. These enzymes play an important role in the process of inflammation that occurs in atopic dermatitis. By blocking the enzymes' action, abrocitinib helps reduce itching and inflammation of the skin.

What benefits of Cibinqo have been shown in studies?

Cibinqo was effective at reducing the extent and severity of atopic dermatitis in three main studies involving patients with moderate to severe disease that had not responded well enough to treatment applied to the skin. The main measures of effectiveness were having clear or almost clear skin and a reduced symptom score of at least 75% after 12 weeks.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

The first study involved 387 adults and children aged 12 years and above. Around 44% of patients taking 200 mg Cibinqo had clear or almost clear skin, compared with 8% of those who received placebo (a dummy treatment). In addition, symptoms were satisfactorily reduced in 63% of patients who received 200 mg Cibinqo, compared with around 12% of those who received placebo.

In the second study, involving 391 adults and children aged 12 years and above, treatment with 200 mg Cibinqo led to clear or almost clear skin in about 38% of the patients compared with around 9% of patients receiving placebo. Symptoms were satisfactorily reduced in 61% of patients taking 200 mg Cibinqo, compared with 10% of those receiving placebo.

In the third study, involving 838 adult patients, treatment with 200 mg Cibinqo led to clear or almost clear skin in around 48% of patients compared with 14% of those receiving placebo. Symptoms were satisfactorily reduced in 70% of patients taking 200 mg Cibinqo, compared with about 27% of patients on placebo.

What are the risks associated with Cibinqo?

The most common side effect with Cibinqo (which may affect more than 1 in 10 people) is nausea (feeling sick). Other common side effects include headache, acne, herpes simplex (viral infection of the mouth or the genitals), increased levels of creatine phosphokinase in the blood (an enzyme released into the blood when muscle is damaged), vomiting, dizziness and pain in the upper belly. The most common serious side effect is infection.

For the full list of side effects of Cibinqo, see the package leaflet.

Cibinqo must not be used in patients who are hypersensitive (allergic) to any of the ingredients, in patients with a serious generalized infection, including tuberculosis, or in patients with severe liver problems. The medicine should also not be used during pregnancy or breast-feeding.

For the full list of restrictions, see the package leaflet.

Why is Cibinqo authorised in the EU?

The European Medicines Agency decided that Cibinqo's benefits are greater than its risks and it can only be authorised for use in adults in the EU.

Three main studies have shown that Cibinqo is effective at clearing the skin and reducing symptoms of atopic dermatitis. The side effects are considered manageable for adults. Due to findings in the bones of juvenile rats, additional long-term data in growing adolescents are needed to conclude that Cibinqo can be safely used by this age group.

What measures are being taken to ensure the safe and effective use of Cibinqo?

The company that markets Cibinqo will provide educational materials for doctors prescribing the medicine and an alert card for patients, containing important information about the risks associated with the medicine. In particular about the risks of infections and of thrombosis (formation of blood clots in the blood vessels) and pulmonary embolism (clot in a blood vessel in the lungs).

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Cibinqo have also been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Cibinqo are continuously monitored. Suspected side effects reported with Cibinqo are carefully evaluated and any necessary action taken to protect patients.

Other information about Cibinqo

Cibinqo received a marketing authorisation valid throughout the EU on 9 December 2021.

Further information on Cibinqo can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/cibinqo

This overview was last updated in 12-2021.