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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 used to treat adults and adolescents from 12 years of age 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 to be taken by mouth once a day. Treatment with Cibinqo may be interrupted if certain side effects occur, including serious infections. Treatment may also be stopped if symptoms have not improved after 24 weeks.

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 action of Janus kinases, abrocitinib helps reduce itching and inflammation of the skin.

What benefits of Cibinqo have been shown in studies?

Cibinqo was effective in reducing the extent and severity of atopic dermatitis in studies involving patients with moderate to severe disease who 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.

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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 124 children aged 12 years and above who were involved in these two studies, results were similar to those seen in adults. Around 22% and 31% of children taking 100 mg or 200 mg Cibinqo, respectively, had clear or almost clear skin, compared with 9% of those given placebo. Symptoms were satisfactorily reduced in around 44% and 56% of patients taking 100 mg or 200 mg Cibinqo, respectively, compared with around 9% of those given 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.

In the fourth study, involving 287 children aged 12 years and above, around 42% and 46% of patients taking 100 mg or 200 mg Cibinqo, respectively, had clear or almost clear skin, compared with around 25% of those taking placebo. Symptoms were satisfactorily reduced in around 69% and 72% of children taking 100 mg or 200 mg Cibinqo, respectively, compared to 42% of those given placebo.

What are the risks associated with Cibinqo?

For the complete list of side effects and restrictions with Cibinqo, see the package leaflet.

The most common side effect with Cibinqo (which may affect more than 1 in 10 people) is nausea (feeling sick). Other common side effects (which may affect up to 1 in 10 people) include headache, acne, herpes simplex (viral infection of the mouth or 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 (which may affect up to 1 in 100 people) is infection.

Cibinqo must not be used in patients with a serious generalized infection, including tuberculosis, or in patients with severe liver problems. The medicine must also not be used during pregnancy or breast-feeding. Women who are able to have children must use contraception during treatment with Cibinqo and for one month after stopping treatment.

Cibinqo should only be used if no suitable treatment alternatives are available in patients aged 65 years or above, in patients with a history of cardiovascular disease (such as heart attack or stroke) or with risk factors for such a disease (such as current or previous long-term smokers), or in patients at increased risk of cancer.

Why is Cibinqo authorised in the EU?

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

Studies have shown that Cibinqo is effective at clearing the skin and reducing symptoms of atopic dermatitis in adults and children aged 12 years and above. In patients for whom Cibinqo is not

contraindicated, the side effects of Cibinqo are considered manageable. At the time of the initial authorisation, there were concerns about a potential effect of Cibinqo on bones in children due to findings in the bones of juvenile rats. Laboratory studies and long-term data in adolescents taking Cibinqo show that there is no risk to bone growth and development in adolescents.

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. Particularly the risks of infections, thrombosis (formation of blood clots in the blood vessels), major cardiovascular events and cancer in certain patients. They will also include a reminder that Cibinqo should not be taken during pregnancy and that women who are able to have children should use contraception during treatment and for one month after stopping treatment.

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 03-2024.