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Cibinqo® (active substance: abrocitinib)

First authorisation in Switzerland: 5 April 2022

Medicinal product (film-coated tablets) for the treatment of moderate to severe atopic dermatitis (neurodermatitis) in adults

About the medicine

Cibinqo contains the active substance abrocitinib and is used for the treatment of adult patients with moderate to severe atopic[1] dermatitis (also known as atopic eczema or neurodermatitis).

Dermatitis is an inflammation of the top layers of the skin that usually manifests as a red, very itchy rash. Up to 8% of all adults are affected by atopic dermatitis. Most cases involve mild forms that can be well controlled with locally applied topical products such as skin ointments. But stubborn forms that can require costly treatments with possible severe side effects also exist.

Therefore, Cibinqo is used only when treatment with conventional, locally applied topical medicinal products is unable to control the disease adequately or cannot be used.
Cibinqo was authorised as part of the joint initiative of the Access Consortium. This joint initiative is a collaborative project between the drug regulatory authorities in Australia (Therapeutic Goods Administration, TGA), Canada (Health Canada, HC), Singapore (Health Sciences Authority, HSA), the United Kingdom (Medicines & Healthcare products Regulatory Agency, MHRA) and Swissmedic and the pharmaceutical industry. The joint initiative coordinates the assessment of authorisation applications for new active substances that have been submitted in at least two of the five countries.

The authorisation application for Cibinqo was submitted to the drug regulatory authorities in Singapore and Switzerland. Each country assessed a part of the application and then shared and discussed the results. At the end of the process, each authority decided on the application independently.

[1] Atopy: Atopy refers to an allergic hypersensitivity to otherwise harmless natural and synthetic substances in the environment.

Mode of action

Cibinqo inhibits "Janus kinases" (JAK), enzymes that are responsible for signal transmission within cells. As a result of this inhibition, the activity of the Janus kinases in the body is decreased, thereby reducing inflammation.

Use

Cibinqo is a prescription-only medicine and is authorised as a tablet containing 50 mg and 100 mg of the active substance abrocitinib.

The recommended initial dose is 1x 100 mg tablet daily. It is recommended that Cibinqo is taken at around the same time each day. The tablet should be swallowed whole with a glass of water, with or without food. The tablet must not be split, crushed or chewed before swallowing.

Efficacy

The efficacy of Cibinqo in the treatment of atopic dermatitis was investigated in three studies with a total of 1,800 patients with at least moderate disease that was not adequately controlled by topical treatment (studies: MONO-1, MONO 2 and COMPARE).

In all three studies, patients received 100 mg Cibinqo alone, in combination with another topical treatment (local treatment in the form of e.g. ointments or creams) or placebo (dummy drug) over a period of 12 to 16 weeks.

The severity of dermatitis is determined by scores achieved on rating scales (IGA and EASI). The corresponding improvements in the scores are also used to confirm the effect in the clinical trials. In the pivotal studies, treatment with Cibinqo was shown to result in an improvement in the atopic dermatitis (significant improvement in scores) compared to treatment with placebo. A faster improvement in the appearance of the skin and the itching was also achieved.

Precautions, undesirable effects & risks

Cibinqo must not be used in those who are hypersensitive to the active substance or any of the excipients.

As a result of the mode of action of Cibinqo, the body's own immune system[2] may be inhibited during long-term treatment with this medicinal product. The use of Cibinqo should be avoided in patients with a serious infection. Before starting treatment with Cibinqo, it should be checked whether important vaccinations are up to date. If necessary, these should be given before starting treatment with Cibinqo.

The most common side effects in all patients treated with Cibinqo were nausea and headache.

There are indications of an increased risk of severe long-term effects with JAK inhibitors (such as increased cardiovascular events or cancer), which are being closely monitored by Swissmedic.

[2] Immune system: The body's defence system against foreign substances and organisms

Cibinqo can cause serious side effects, which the doctor should be informed of immediately (e.g. shortness of breath, bloody sputum, weight loss, burning sensation on urination or more frequent need to urinate).

Treatment with Cibinqo should be discontinued if no improvement is visible after 12 weeks at the latest.

All precautions, risks and other possible undesirable effects are listed in the Information for patients (package leaflet) and the Information for healthcare professionals.

Why the medicine has been authorised

The completed studies showed a benefit for Cibinqo, compared to placebo (dummy drug), in the treatment of atopic dermatitis in adults with at least moderate disease.

Based on all the available data, the benefits of Cibinqo outweigh the risks if used correctly in appropriately selected patients.

Swissmedic has therefore authorised the medicinal product Cibinqo for the treatment of adult patients with at least moderate atopic dermatitis when locally applied topical medicinal products are unable to control the disease adequately or cannot be used.

Further information on the medicinal product

Information for healthcare professionals: Information for healthcare professionals Cibinqo®

Information for patients (package leaflet): Information for patients Cibinqo®

Healthcare professionals can answer any further questions.

The date of revision of this text corresponds to that of the SwissPAR. New information concerning the authorised medicinal product in question will not be incorporated into the Public Summary SwissPAR.

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