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Staquis (*crisaborole*)

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

What is Staquis and what is it used for?

Staquis is a medicine used to treat adults and children from 2 years of age with mild to moderate atopic dermatitis (also known as eczema, when the skin is itchy, red and dry). Staquis is used when the dermatitis affects up to 40% of the body's surface.

Staquis contains the active substance crisaborole.

How is Staquis used?

Staquis can only be obtained with a prescription. It is available as an ointment to be applied on the affected skin, excluding the scalp, twice a day for up to 4 weeks. Further 4-week treatment courses can be used if symptoms continue or new areas affected by the disease appear. Staquis should be stopped if symptoms of atopic dermatitis are still present after 12 consecutive weeks of treatment.

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

How does Staquis work?

Patients with atopic dermatitis produce high levels of proteins called cytokines, which can cause the inflammation of the skin seen in dermatitis. The active substance in Staquis, crisaborole, blocks the release of certain cytokines involved in the inflammation process such as tumour necrosis factor alpha, interleukins (IL-2, IL-4, IL-5), and interferon gamma. By blocking their release, crisaborole is expected to ease the inflammation and therefore relieve symptoms of the disease.

What benefits of Staquis have been shown in studies?

Staquis was effective at clearing up the skin of patients with mild to moderate atopic dermatitis in two main studies involving a total of 1,527 adults and children from 2 years of age. In one study, treatment with Staquis led to clear or almost clear skin in around 33% of patients, compared with 25% of patients who used a dummy treatment. In the second study, Staquis led to clear or almost clear skin in 31% of patients versus 18% with the dummy treatment.

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What are the risks associated with Staquis?

The most common side effects with Staquis (which may affect up to 1 in 10 people) are reactions at the application site (including burning or stinging).

For the full list of side effects and restrictions of Staquis, see the package leaflet.

Why is Staquis authorised in the EU?

Staquis was shown to be effective at clearing up the skin of patients with mild to moderate atopic dermatitis. The side effects of Staquis were mostly mild or moderate and short-lived. Patients with more than 40% of their skin affected experienced side effects more frequently, which is why these patients should not use Staquis.

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

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

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

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

Other information about Staquis

Staquis received a marketing authorisation valid throughout the EU on 27 March 2020.

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

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