EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

30 January 2020
EMA/CHMP/35206/2020
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Staquis

crisaborole

On 30 January 2020, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Staquis, intended for the treatment of atopic dermatitis. The applicant for this medicinal product is Pfizer Europe MA EEIG.

Staquis will be available as 20 mg/g ointment. The active substance of Staquis is crisaborole, a non-corticosteroid dermatological agent for dermatitis, (ATC code: D11AH). Staquis is a phosphodiesterase-4 (PDE4) inhibitor that suppresses secretion of certain cytokines, such as tumour necrosis factor-α (TNF-α), interleukins (IL-2, IL-4, IL-5), and interferon gamma (IFNγ) and improves skin barrier function through its anti -inflammatory effects.

The benefits with Staquis are its ability to provide clinical improvement in mild to moderate atopic dermatitis patients with less than 40% body surface area affected. The most common side effects are application site reactions, including application site pain, e.g., burning or stinging.

The full indication is:

"Staquis is indicated for treatment of mild to moderate atopic dermatitis in adults and paediatric patients from 2 years of age with ≤ 40% body surface area (BSA) affected".

Staquis should be prescribed by physicians experienced in the treatment of atopic dermatitis.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

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