19 December 2013
EMA/CHMP/684313/2013
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Mirvaso

Brimonidine tartrate

On 19 December 2013, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Mirvaso, 3 mg/g, gel, intended for the symptomatic treatment of facial erythema of rosacea in adult patients. The applicant for this medicinal product is Galderma International. They may request a re-examination of any CHMP opinion, provided they notify the European Medicines Agency in writing of their intention within 15 days of receipt of the opinion.

The active substance of Mirvaso, brimonidine tartrate, under the ATC group 'other dermatologicals', is a relatively selective alpha-2 adrenergic agonist, with potent vasoconstrictive / vasostabilising activity. Erythema of rosacea is linked to permanent vasodilatation of small vessels. Reduction of facial erythema is obtained by vasoconstriction mediated by influence on postsynaptic smooth muscle alpha-2 adrenergic receptors stimulation.

The benefits with Mirvaso are its ability to demonstrate statistical superiority ($p<0.001$) over vehicle gel with respect to rapid initial onset of a clinically meaningful effect (1-Grade Composite Success for CEA and PSA) after the first application at 30 minutes on Day 1, and to achievement of a clinically meaningful effect (1-Grade Composite Success for CEA and PSA) at hours 3, 6, 9, and 12 on Day 29 this has been demonstrated in two randomised, vehicle controlled clinical trials, which were identical in design. The most common local adverse events associated with topical use of brimonidine tartrate are erythema, pruritus, flushing and skin burning sensation.

A pharmacovigilance plan for Mirvaso will be implemented as part of the marketing authorisation.

The approved indication is: "Mirvaso is indicated for the symptomatic treatment of facial erythema of rosacea in adult patients."

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

[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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made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

The CHMP, on the basis of quality, safety and efficacy data submitted, considers there to be a favourable benefit-to-risk balance for Mirvaso and therefore recommends the granting of the marketing authorisation.