15 October 2020
EMA/CHMP/114257/2020
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Desloratadine ratiopharm

desloratadine

On 15 October 2020, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending a change to the terms of the marketing authorisation for the medicinal product Desloratadine ratiopharm. The marketing authorisation holder for this medicinal product is ratiopharm GmbH.

The variation concerns a change in the classification of Desloratadine ratiopharm from "medicinal product subject to medical prescription" to "medicinal product not subject to medical prescription".

This change is based on the fact that CHMP agreed that the criteria for classifying a medicine as subject to medical prescription as laid down in the European Commission Guideline do not apply to Desloratadine ratiopharm. Therefore, the Committee recommended that the change in the supply classification is approvable.

As a consequence of this change, CHMP agreed to limit the indications to adults only and to restrict the urticaria indication to chronic idiopathic urticaria as initially diagnosed by a physician. The CHMP adopted a change to the existing indications as follows:[2]

> Desloratadine ratiopharm ~~**5 mg film-coated tablets**~~ is indicated in adults ~~**and adolescents aged 12 years and older**~~ for the relief of symptoms associated with:
>
> - allergic rhinitis (see section 5.1)
>
> - **chronic idiopathic** urticaria **as initially diagnosed by a physician** (see section 5.1)

Detailed recommendations for the use of this product will be described in the updated summary of product characteristics (SmPC), which will be published in the revised European public assessment report (EPAR), and will be available in all official European Union languages after a decision on this change to 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

[2] New text in **bold**, removed text as ~~strikethrough~~

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