17 September 2020
EMA/CHMP/487691/2020
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Orfadin

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On 17 September 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 Orfadin. The marketing authorisation holder for this medicinal product is Swedish Orphan Biovitrum International AB.

The CHMP adopted a new indication for the treatment of adult patients with alkaptonuria.

For information, the full indications for Orfadin will be as follows:[2]

Hereditary tyrosinemia type 1 (HT-1)

Orfadin is indicated for the treatment of adult and paediatric (in any age range) patients with confirmed diagnosis of hereditary tyrosinemia type 1 (HT-1) in combination with dietary restriction of tyrosine and phenylalanine.

Alkaptonuria (AKU)

Orfadin is indicated for the treatment of adult patients with alkaptonuria (AKU).

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**

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