EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

26 July 2018
EMA/CHMP/432508/2018
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Deferiprone Lipomed

deferiprone

On 26 July 2018, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Deferiprone Lipomed, intended for the treatment of iron overload in patients with thalassaemia major. The applicant for this medicinal product is Lipomed GmbH.

Deferiprone Lipomed will be available as 500-mg film-coated tablets. The active substance of Deferiprone Lipomed is deferiprone, an iron chelating agent (ATC code: V03AC02) which binds to iron in a 3 to 1 molar ratio.

Deferiprone Lipomed is a generic of Ferriprox, which has been authorised in the EU since 25 August 1999. Studies have demonstrated the satisfactory quality of Deferiprone Lipomed and its bioequivalence to the reference product Ferriprox. A question and answer document on generic medicines can be found here.

The full indication is:

> "Deferiprone Lipomed monotherapy is indicated for the treatment of iron overload in patients with thalassaemia major when current chelation therapy is contraindicated or inadequate.
>
> Deferiprone Lipomed in combination with another chelator (see section 4.4) is indicated in patients with thalassaemia major when monotherapy with any iron chelator is ineffective, or when prevention or treatment of life-threatening consequences of iron overload justifies rapid or intensive correction (see section 4.2)."

It is proposed that Deferiprone Lipomed be prescribed by physicians experienced in the treatment of patients with thalassaemia.

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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