



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (initial authorisation)

Deferasirox Mylan deferasirox

On 25 July 2019, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Deferasirox Mylan, intended for the treatment of chronic iron overload due to blood transfusions in patients with beta thalassaemia major, non-transfusion-dependent thalassaemia syndromes and other anaemias. The applicant for this medicinal product is Mylan S.A.S.

Deferasirox Mylan will be available as 90 mg, 180 mg and 360 mg film-coated tablets. The active substance of Deferasirox Mylan is deferasirox, an iron binding agent (ATC code: V03AC03) that is highly selective for iron (III) and promotes excretion of iron primarily in the faeces.

Deferasirox Mylan is a generic of Exjade, which has been authorised in the EU since 28 August 2006. Studies have demonstrated satisfactory quality of Deferasirox Mylan, and its bioequivalence to the reference product Exjade. A question and answer document on generic medicines can be found [here](#).

The full indication is:

“Deferasirox Mylan is indicated for the treatment of chronic iron overload due to frequent blood transfusions (≥ 7 ml/kg/month of packed red blood cells) in patients with beta thalassaemia major aged 6 years and older.

Deferasirox Mylan is also indicated for the treatment of chronic iron overload due to blood transfusions when deferoxamine therapy is contraindicated or inadequate in the following patient groups:

- in paediatric patients with beta thalassaemia major with iron overload due to frequent blood transfusions (> 7 ml/kg/month of packed red blood cells) aged 2 to 5 years,
- in adult and paediatric patients with beta thalassaemia major with iron overload due to infrequent blood transfusions (< 7 ml/kg/month of packed red blood cells) aged 2 years and older,
- in adult and paediatric patients with other anaemias aged 2 years and older.

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



Deferasirox Mylan is also indicated for the treatment of chronic iron overload requiring chelation therapy when deferoxamine therapy is contraindicated or inadequate in patients with non-transfusion-dependent thalassaemia syndromes aged 10 years and older.”

It is proposed that Deferasirox Mylan be prescribed by physicians experienced in the treatment of chronic iron overload.

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.