14 November 2019
EMA/CHMP/590490/2019
Committee for Medicinal Products for Human Use (CHMP)

**Summary of opinion[1] (initial authorisation)**

# Deferasirox Accord

deferasirox

On 14 November 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 Accord, intended for the treatment of chronic iron overload due to blood transfusions in patients with beta thalassaemia and other anaemias. The applicant for this medicinal product is Accord Healthcare S.L.U.

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

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

The full indication is:

"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 Accord 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.

Deferasirox Accord 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."

[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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It is proposed that Deferasirox Accord 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.