30 January 2025
EMA/CHMP/563278/2024
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Eltrombopag Accord

eltrombopag

On 30 January 2025, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Eltrombopag Accord, intended for the treatment of adults and children with primary immune thrombocytopenia (ITP) and thrombocytopenia associated with chronic hepatitis C. The applicant for this medicinal product is Accord Healthcare S.L.U.

Eltrombopag Accord will be available as 12.5 mg, 25 mg, 50 mg and 75 mg film-coated tablets. The active substance of Eltrombopag Accord is eltrombopag, an antihemorrhagic (ATC code: B02BX05). Eltrombopag interacts with the transmembrane domain of the human thrombopoietin (TPO) receptor, triggering signalling cascades that are similar to those triggered by TPO. This interaction induces the proliferation and differentiation of bone marrow progenitor cells.

Eltrombopag Accord is a generic of Revolade, which has been authorised in the EU since 11 March 2010. Studies have demonstrated the satisfactory quality of Eltrombopag Accord, and its bioequivalence to the reference product Revolade. A question and answer document on generic medicines can be found here.

The full indication is:

> Eltrombopag Accord is indicated for the treatment of adult patients with primary immune thrombocytopenia (ITP) who are refractory to other treatments (e.g. corticosteroids, immunoglobulins) (see sections 4.2 and 5.1).
>
> Eltrombopag Accord is indicated for the treatment of paediatric patients aged 1 year and above with primary immune thrombocytopenia (ITP) lasting 6 months or longer from diagnosis and who are refractory to other treatments (e.g. corticosteroids, immunoglobulins) (see sections 4.2 and 5.1).
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> Eltrombopag Accord is indicated in adult patients with chronic hepatitis C virus (HCV) infection for the treatment of thrombocytopenia, where the degree of thrombocytopenia is the main

[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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factor preventing the initiation or limiting the ability to maintain optimal interferon-based therapy (see sections 4.4 and 5.1).

Treatment with Eltrombopag Accord should be prescribed and supervised by a doctor experienced in the treatment of haematological diseases or the management of chronic hepatitis C and its complications.

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.