EMA/65887/2025
EMEA/H/C/006459

Eltrombopag Accord (*eltrombopag*)

An overview of Eltrombopag Accord and why it is authorised in the EU

What is Eltrombopag Accord and what is it used for?

Eltrombopag Accord is a medicine used for the treatment of:

- primary immune thrombocytopenia (ITP), a disease in which the patient's immune system destroys platelets (components in the blood that help it to clot). Patients with ITP have low platelet counts in the blood (thrombocytopenia) and are at risk of bleeding. Eltrombopag Accord is used in patients from 1 year of age for whom treatment with medicines such as corticosteroids or immunoglobulins has not worked. In children and adolescents, the medicine is used when they have had the disease for at least 6 months;
- thrombocytopenia in adults with chronic (long-term) hepatitis C, a liver disease caused by the hepatitis C virus. Eltrombopag Accord is used when the thrombocytopenia is too severe to allow interferon-based therapy (a type of treatment for hepatitis C).

Eltrombopag Accord contains the active substance eltrombopag and is a 'generic medicine'. This means that Eltrombopag Accord contains the same active substance and works in the same way as a 'reference medicine' already authorised in the EU. The reference medicine for Eltrombopag Accord is Revolade. For more information on generic medicines, see the question-and-answer document here.

How is Eltrombopag Accord used?

Eltrombopag Accord is available as tablets to be taken by mouth. The medicine can only be obtained with a prescription and treatment should be started and supervised by a doctor who has experience in treating blood diseases or chronic hepatitis C and its complications.

The dose depends on the patient's age and the disease for which Eltrombopag Accord is being used; it is adjusted as needed to maintain an appropriate platelet level.

For more information about using Eltrombopag Accord, see the package leaflet or contact your doctor or pharmacist.

How does Eltrombopag Accord work?

In the body, a hormone called thrombopoietin stimulates the production of platelets by attaching to certain receptors (targets) in the bone marrow. The active substance in Eltrombopag Accord,

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eltrombopag, also attaches to and stimulates the thrombopoietin receptors. This increases the production of platelets, improving platelet counts.

How has Eltrombopag Accord been studied?

Studies on the benefits and risks of the active substance in the authorised uses have already been carried out with the reference medicine, Revolade, and do not need to be repeated for Eltrombopag Accord.

As for every medicine, the company provided studies on the quality of Eltrombopag Accord. The company also carried out a study that showed that it is 'bioequivalent' to the reference medicine. Two medicines are bioequivalent when they produce the same levels of the active substance in the body and are therefore expected to have the same effect.

What are the benefits and risks of Eltrombopag Accord?

Because Eltrombopag Accord is a generic medicine and is bioequivalent to the reference medicine, its benefits and risks are taken as being the same as the reference medicine's.

Why is Eltrombopag Accord authorised in the EU?

The European Medicines Agency concluded that, in accordance with EU requirements, Eltrombopag Accord has been shown to have comparable quality and to be bioequivalent to Revolade. Therefore, the Agency's view was that, as for Revolade, the benefits of Eltrombopag Accord outweigh the identified risks and it can be authorised for use in the EU.

What measures are being taken to ensure the safe and effective use of Eltrombopag Accord?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Eltrombopag Accord have been included in the summary of product characteristics and the package leaflet. Any additional measures in place for Revolade also apply to Eltrombopag Accord where appropriate.

As for all medicines, data on the use of Eltrombopag Accord are continuously monitored. Suspected side effects reported with Eltrombopag Accord are carefully evaluated and any necessary action taken to protect patients.

Other information about Eltrombopag Accord

Eltrombopag Accord received a marketing authorisation valid throughout the EU on 28 March 2025.

Further information on Eltrombopag Accord can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/eltrombopag-accord. Information on the reference medicine can also be found on the Agency's website.

This overview was updated in 03-2025.