LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Eltrombopag Bioglan
(eltrombopag olamine, eltrombopag)

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Postadress/Postal address: P.O. Box 26, SE-751 03 Uppsala, SWEDEN
Besöksadress/Visiting address: Dag Hammarskjölds väg 42, Uppsala
Telefon/Phone: +46 (0)18 17 46 00 Fax: +46 (0)18 54 85 66
Internet: www.lakemedelsverket.se E-mail: registrator@lakemedelsverket.se

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Film-coated tablet, 25 mg, 50 mg

This is a summary of the public assessment report (PAR) for Eltrombopag Bioglan. It explains how the assessment was made and why the authorisation was recommended as well as the conditions of use. It is not intended to provide practical advice on how to use the product.

For practical information about the use of the product, patients should read the package leaflet or contact their doctor or pharmacist.

What is Eltrombopag Bioglan and what is it used for?
The product is a 'generic medicine'. This means that it is similar to a 'reference medicine' already authorised in the European Union (EU) called Revolade.

The product is used in the treatment of:

- Eltrombopag Bioglan is used to treat a bleeding disorder called immune (primary) thrombocytopenia (ITP) in patients aged 1 year and above who have already taken other medicines (corticosteroids or immunoglobulins), which have not worked.

  ITP is caused by a low blood platelet count (thrombocytopenia). People with ITP have an increased risk of bleeding. Symptoms patients with ITP may notice include petechiae (pinpoint-sized flat round red spots under the skin), bruising, nosebleeds, bleeding gums and not being able to control bleeding if they are cut or injured.

- Eltrombopag Bioglan can also be used to treat low platelet count (thrombocytopenia) in adults with hepatitis C virus (HCV) infections, if they have had problems with side effects while on interferon treatment. Many people with hepatitis C have low platelet counts, not only as a result of the disease, but also due to some of the antiviral medicines that are used to treat it. Taking Eltrombopag Bioglan may make it easier for you to complete a full course of antiviral medicine (peginterferon and ribavirin).

- Eltrombopag Bioglan may also be used to treat adult patients with low blood counts caused by severe aplastic anaemia (SAA). SAA is a disease in which the bone marrow is damaged, causing a deficiency of the red blood cells (anaemia), white blood cells (leukopenia) and platelets (thrombocytopenia).

How does Eltrombopag Bioglan work?

Eltrombopag Bioglan contains eltrombopag, which belongs to a group of medicines called thrombopoietin-receptor agonists. It is used to help increase the number of platelets in your blood. Platelets are blood cells that help to reduce or prevent bleeding.

How is Eltrombopag Bioglan used?

The pharmaceutical form is film-coated tablet for oral use.

Please read section 3 of the package leaflet for detailed information on dosing recommendations, the route of administration, and the duration of treatment.

The medicine can only be obtained with a prescription in Sweden.

What benefits of Eltrombopag Bioglan have been shown in studies?

Because the product is a generic medicine, studies in patients have been limited to tests to determine that it is bioequivalent to the reference medicine, Revolade. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

What are the possible side effects from Eltrombopag Bioglan?
Because the product is a generic medicine, its benefits and possible side effects are taken as being the same as the reference medicine.

For the full list of side effects, see section 4 of the package leaflet.

For the full list of restrictions, see the package leaflet.

Why is Eltrombopag Bioglan approved?

It was concluded that, in accordance with EU requirements, the product has been shown to have comparable quality and is considered to be bioequivalent to the reference medicine. Therefore, the Swedish Medical Products Agency decided that, as for Revolade, the benefits are greater than its risks and recommended that it can be approved for use.

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

A risk management plan has been developed to ensure that the product is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet, including the appropriate precautions to be followed by healthcare professionals and patients.

Known side effects are continuously monitored. Furthermore, new safety signals reported by patients/healthcare professionals will be monitored/reviewed continuously as well.

Other information about Eltrombopag Bioglan

The full PAR for Eltrombopag Bioglan can be found on the following website: http://mri.medagencies.org/Human/. For more information about treatment with Eltrombopag Bioglan , please read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in 2024-08.