Part VI: Summary of the risk management plan

Summary of risk management plan for Eltrombopag Bioglan

This is a summary of the risk management plan (RMP) for Eltrombopag Bioglan. The RMP details important risks of Eltrombopag Bioglan, how these risks can be minimised, and how more information will be obtained about Eltrombopag Bioglan's risks and uncertainties (missing information).

Eltrombopag Bioglan's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Eltrombopag Bioglan should be used.

I. The medicine and what it is used for

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. 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. Eltrombopag Bioglan may also be used to treat adult patients with low blood counts caused by severe aplastic anaemia (SAA) (see SmPC for the full indication). It contains eltrombopag as the active substance and it is given by the oral route.

II. Risks associated with the medicine and activities to minimise or further characterise the risks

Important risks of Eltrombopag Bioglan, together with measures to minimise such risks and the proposed studies for learning more about Eltrombopag Bioglan's risks, are outlined below.

Measures to minimise the risks identified for medicinal products can be:

- Specific information, such as warnings, precautions, and advice on correct use, in the package leaflet and SmPC addressed to patients and healthcare professionals;
- Important advice on the medicine's packaging;
- The authorised pack size - the amount of medicine in a pack is chosen so to ensure that the medicine is used correctly;
- The medicine's legal status - the way a medicine is supplied to the patient (e.g. with or without prescription) can help to minimise its risks.

Together, these measures constitute routine risk minimisation measures.

In addition to these measures, information about adverse reactions is collected continuously and regularly analysed so that immediate action can be taken as necessary. These measures constitute routine pharmacovigilance activities.

If important information that may affect the safe use of Eltrombopag Bioglan is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Eltrombopag Bioglan are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely taken. Important risks can be regarded as identified or potential. Identified risks are concerns for which there is sufficient proof of a link with the use of Eltrombopag Bioglan. Potential risks are concerns for which an association with the use of this medicine is possible based on available data, but this association has not been established yet and needs further evaluation. Missing information refers to information on the safety of the medicinal product that is currently missing and needs to be collected (e.g. on the long-term use of the medicine);

Summary of safety concerns	
Important identified risks	**Adult ITP, Paediatric ITP, HCV-associated thrombocytopenia and severe aplastic anaemia** • Hepatotoxicity • Thromboembolic events **HCV-associated thrombocytopenia** • Hepatic decompensation
Important potential risks	**Adult ITP, Paediatric ITP, and HCV-associated thrombocytopenia and severe aplastic anaemia** • Increased Bone Marrow Reticulin Formation • Haematological malignancies **Severe aplastic anaemia** • Cytogenetic abnormalities
Missing information	**Adult ITP, Paediatric ITP, and HCV-associated thrombocytopenia and severe aplastic anaemia** • Patients with hepatic impairment • Use in paediatric population

II.B Summary of important risks

The safety information in the proposed Product Information is aligned to the reference medicinal product.

II.C Post-authorisation development plan

II.C.1 Studies which are conditions of the marketing authorisation

There are no studies which are conditions of the marketing authorisation or specific obligation of Eltrombopag Bioglan.

II.C.2 Other studies in post-authorisation development plan

There are no studies required for Eltrombopag Bioglan.