Part VI: Summary of the risk management plan

Summary of risk management plan for Eltrombopag 12.5 mg, 25 mg, 50 mg and 75 mg film coated tablets (Eltrombopag)

This is a summary of the risk management plan (RMP) for Eltrombopag 12.5 mg, 25 mg, 50 mg and 75 mg film-coated tablets. The RMP details important risks of Eltrombopag, how these risks can be minimised, and how more information will be obtained about Eltrombopag risks and uncertainties (missing information).

Eltrombopag´s Summary of Product Characteristics (SmPC) and its Package Leaflet (PL) gives essential information to healthcare professionals and patients on how the tablets should be used.

I. The medicine and what it is used for

Eltrombopag is used to treat a bleeding disorder called immune (primary) thrombocytopenia (ITP) in adult patients who have already taken other medicines (corticosteroids or immunoglobulins), which have not worked.

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

Eltrombopag may 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.

This medicine 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).[2]

It contains eltrombopag as the active substance and it is given by oral route of administration.

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

Important risks of Eltrombopag, together with measures to minimise such 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.

[2] *The product may not be approved in your country for severe aplastic anaemia. Please check the patient information leaflet.”*

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

II.A List of important risks and missing information

Important risks of Eltrombopag are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely administered.

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. 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).

List of important risks and missing information*	
Important identified risks	• **Adult ITP, Paediatric ITP, HCV-associated thrombocytopenia and severe aplastic anaemia** ✓ Hepatotoxicity (liver damage) ✓ Thromboembolic events (risk of blood clots) • **HCV-associated thrombocytopenia** ✓ Hepatic decompensation (liver problems)
Important potential risks	• **Adult ITP, Paediatric ITP, and HCV-associated thrombocytopenia and severe aplastic anaemia** ✓ Increased bone marrow reticulin formation (bone marrow abnormalities) ✓ Haematological malignancies (blood cell cancers) • **Severe aplastic anaemia** ✓ Cytogenetic abnormalities (risk for severe aplastic anaemia)
Missing information	• **Adult ITP, Paediatric ITP, and HCV-associated thrombocytopenia and severe aplastic anaemia** ✓ Patients with hepatic impairment (decreased liver function) • **Severe aplastic anaemia** ✓ Use in paediatric population (Children)

**The product may not be approved in your country for severe aplastic anaemia. Please check the patient information leaflet."*

II.B Summary of important risks

The safety information in the proposed Product Information is aligned to that of 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.

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

There are no studies required for Eltrombopag.