PART VI: SUMMARY OF THE RISK MANAGEMENT PLAN

Summary of Risk Management Plan for Eltrombopag Vale (eltrombopag)

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

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

Important new concerns or changes to the current ones will be included in updates of Eltrombopag Vale's RMP.

I. The Medicine and What it is Used For

Eltrombopag Vale is authorised for.

- For the treatment of adult patients with primary immune thrombocytopenia (ITP) who are refractory to other treatments (e.g., corticosteroids, immunoglobulins).

- 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).

- In adult patients with chronic hepatitis C virus (HCV) infection for the treatment of thrombocytopenia, where the degree of thrombocytopenia is the main factor preventing the initiation or limiting the ability to maintain optimal interferon-based therapy.

- In adult patients with acquired severe aplastic anaemia (SAA) who were either refractory to prior immunosuppressive therapy or heavily pretreated and are unsuitable for haematopoietic stem cell transplantation.

II. Risks Associated with the Medicine and Activities to Minimise or Further Characterise the Risks

Important risks of Eltrombopag Vale, together with measures to minimise such risks and the proposed studies for learning more about Eltrombopag Vale, 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 public (e.g., with or without prescription) can help to minimises its risks.

Together, these measures constitute routine risk minimisation measures.

In addition to these measures, information about adverse events 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 Vale is not yet available, it is listed under 'missing information' below.

II.A List of Important Risks and Missing Information

Important risks of Eltrombopag Vale are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely taken by patients. 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 Vale. 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/use in special patient populations etc.).

Table 6: Part VI.1- Summary of safety concerns

List of important risks and missing information	
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, 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, HCV-associated thrombocytopenia, and severe aplastic anaemia*** • Patients with hepatic impairment ***Severe aplastic anaemia*** • Use in paediatric population

II.B Summary of Important Risks

Table 7: Part VI.2- Hepatotoxicity

Evidence for Linking the Risk to the Medicine	In line with the reference RMP, this safety concern has been classified as an important identified risk.

Risk Factors and Risk Groups	Not applicable
Risk Minimisation Measures	Routine risk minimization measures: SmPC section 4.2, 4.4 and 4.8. PL section 4.
Additional risk minimisation measures	None

Table 8: Part VI.2- Thromboembolic events

Evidence for Linking the Risk to the Medicine	In line with the reference RMP, this safety concern has been classified as an important identified risk.
Risk Factors and Risk Groups	Not applicable
Risk Minimisation Measures	Routine risk minimization measures: SmPC section 4.2, 4.4, 4.8 and 4.9 PL section 2 and 4.
Additional risk minimisation measures	None

Table 9: Part VI.2 - Hepatic decompensation

Evidence for Linking the Risk to the Medicine	In line with the reference RMP, this safety concern has been classified as an important identified risk.
Risk Factors and Risk Groups	Not applicable
Risk Minimisation Measures	Routine risk minimization measures: SmPC section 4.2, 4.8. PL section 4.
Additional risk minimisation measures	None

Table 10: Part VI.2 - Increased Bone Marrow Reticulin Formation

Evidence for Linking the Risk to the Medicine	In line with the reference RMP, this safety concern has been classified as an important identified risk.
Risk Factors and Risk Groups	Not applicable
Risk Minimisation Measures	Routine risk minimization measures: SmPC section 4.2, 4.4, 4.8. PL section 4.
Additional risk minimisation measures	None

Table 11: Part VI.2 - Haematological malignancies

Evidence for Linking the Risk to the Medicine	In line with the reference RMP, this safety concern has been classified as an important identified risk.
Risk Factors and Risk Groups	Not applicable
Risk Minimisation Measures	Routine risk minimization measures: SmPC section 4.2, 4.8. PL section 4.
Additional risk minimisation measures	None

Table 12: Part VI.2 - Cytogenetic abnormalities

Evidence for Linking the Risk to the Medicine	In line with the reference RMP, this safety concern has been classified as an important potential risk.
Risk Factors and Risk Groups	Not applicable
Risk Minimisation Measures	Routine risk minimization measures: SmPC section 4.2 PL section 4.
Additional risk minimisation measures	None

Table 13: Part VI.2 - Patients with hepatic impairment

Evidence for Linking the Risk to the Medicine	In line with the reference RMP, this safety concern has been classified as missing information.
Risk Factors and Risk Groups	Not applicable
Risk Minimisation Measures	Routine risk minimization measures: SmPC section 4.2 PL section 4.
Additional risk minimisation measures	None

Table 14: Part VI.2 - Use in paediatric population

Evidence for Linking the Risk to the Medicine	In line with the reference RMP, this safety concern has been classified as missing information.
Risk Factors and Risk Groups	Not applicable
Risk Minimisation Measures	Routine risk minimization measures: SmPC section 4.2 PL section 2
Additional risk minimisation measures	None

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 Vale.

II.C.2 Other Studies in Post-Authorisation Development Plan

There are no studies required for Eltrombopag Vale.