

Souhrn plánu řízení rizik podle § 99 odst. 8 písm. a) zákona č. 378/2007 Sb., o léčivech a o změnách některých souvisejících zákonů (zákon o léčivech), ve znění pozdějších předpisů (1)

Eltrombopag Abdi 25 mg potahované tablety

Eltrombopag Abdi 50 mg potahované tablety

Eltrombopag Abdi 75 mg potahované tablety

Administrativní informace:

Léčivá látka/látky	Eltrombopag-olamin
Léková forma/formy	Potahovaná tableta
Síla/síly	25 mg, 50 mg, 75 mg
Držitel rozhodnutí o registraci	Abdi Farma GmbH
Registrační číslo/čísla	16/069/23-C 16/070/23-C 16/071/23-C
Verze a datum plánu řízení rizik	1.0, 18/12/2024

Následující výňatek z plánu řízení rizik (RMP) výše uvedeného léčivého přípravku/léčivých přípravků je souhrnem podstatných informací uvedených ve zmíněném RMP. RMP popisuje opatření, která mají být přijata, aby bylo zajištěno, že tento léčivý přípravek/tyto léčivé přípravky budou používány co nejbezpečněji. Souhrn RMP je potřeba číst spolu se schváleným souhrnem údajů o přípravku/přípravcích a příbalovou informací.

Tento souhrn RMP připravil Státní ústav pro kontrolu léčiv za účelem splnění své zákonné povinnosti týkající se transparentnosti vůči veřejnosti.

1) [Zákon č. 378/2007 Sb., o léčivech, ve znění pozdějších předpisů](#)

Summary of risk management plan for Eltrombopag Abdi 25 mg, 50 mg and 75 mg Film Coated Tablet (eltrombopag)

This is a summary of the risk management plan (RMP) for Eltrombopag Abdi 25 mg, 50 mg and 75 mg Film Coated Tablet. The RMP details important risks of Eltrombopag Abdi 25 mg, 50 mg and 75 mg Film Coated Tablet, how these risks can be minimised, and how more information will be obtained about Eltrombopag Abdi 25 mg, 50 mg and 75 mg Film Coated Tablet's risks and uncertainties (missing information).

Eltrombopag Abdi 25 mg, 50 mg and 75 mg Film Coated Tablet's summary of product characteristics (SmPC) and its package leaflet (PL) give essential information to healthcare professionals and patients on how Eltrombopag Abdi 25 mg, 50 mg and 75 mg Film Coated Tablet should be used.

Important new concerns or changes to the current ones will be included in updates of Eltrombopag Abdi 25 mg, 50 mg and 75 mg Film Coated Tablet's RMP.

I. The medicine and what it is used for

Eltrombopag Abdi 25 mg, 50 mg and 75 mg Film Coated Tablet are authorised for the treatment of adult patients with primary immune thrombocytopenia (ITP) who are refractory to other treatments (e.g. corticosteroids, immunoglobulins), and paediatric patients aged 1 year and above with primary ITP lasting 6 months or longer from diagnosis and who are refractory to other treatments (e.g. corticosteroids, immunoglobulins). They are also authorised 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 (see SmPC for the full indication).

It contains Eltrombopag olamine 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 Abdi 25 mg, 50 mg and 75 mg Film Coated Tablet, together with measures to minimise such risks and the proposed studies for learning more about Eltrombopag Abdi 25 mg, 50 mg and 75 mg Film Coated Tablet'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 a 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 Abdi 25 mg, 50 mg and 75 mg Film Coated Tablet, is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Eltrombopag Abdi 25 mg, 50 mg and 75 mg Film Coated Tablet 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 Abdi 25 mg, 50 mg and 75 mg Film Coated Tablet. 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	<p>Adult ITP (Immune thrombocytopenia), Paediatric ITP, HCV (Hepatitis C virus) – associated thrombocytopenia and severe aplastic anaemia</p> <ul style="list-style-type: none"> • Hepatotoxicity • Thromboembolic events <p>HCV-associated thrombocytopenia</p> <ul style="list-style-type: none"> • Hepatic decompensation
Important potential risks	<p>Adult ITP, Paediatric ITP, and HCV-associated thrombocytopenia and severe aplastic anaemia</p> <ul style="list-style-type: none"> • Increased Bone Marrow Reticulin Formation • Haematological malignancies <p>Severe aplastic anaemia</p> <ul style="list-style-type: none"> • Cytogenetic Abnormalities

Missing information	<p>Adult ITP, Paediatric ITP, and HCV-associated thrombocytopenia and severe aplastic anaemia</p> <ul style="list-style-type: none"> • Patients with hepatic impairment <p>Severe aplastic anaemia</p> <ul style="list-style-type: none"> • Use in paediatric population
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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 Abdi 25 mg, 50 mg and 75 mg Film Coated Tablet.

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

There are no studies required for Eltrombopag Abdi 25 mg, 50 mg and 75 mg Film Coated Tablet.