Eltrombopag Accord

Procedural steps taken and scientific information after the authorisation*

*Due to the Agency`s update of its procedure management systems, an additional document, reflecting the historical lifecycle may be available in the 'Assessment history' section. For the complete product lifecycle procedures, you may need to also refer to **EPAR - Procedural steps taken and scientific information after authorisation (archive)**.

Application number	Scope	Opinion/ Notification [1] issued on	Commission Decision Issued [2] / amended on	Product Information affected [3]	Summary
Variation type IB /	Outcome:	21/07/2026			

[1] Notifications are issued for type I variations and Article 61(3) notifications (unless part of a group including a type II variation or extension application or a worksharing application). Opinions are issued for all other procedures.
[2] A Commission decision (CD) is issued for procedures that affect the terms of the marketing authorisation (e.g. summary of product characteristics, annex II, labelling, package leaflet). The CD is issued within two months of the opinion for variations falling under the scope of Article 23.1a(a) of Regulation (EU) No. 712/2012, or within one year for other procedures.
[3] SmPC (Summary of Product Characteristics), Annex II, Labelling, PL (Package Leaflet).

EMA/VR/0000357780	C.9 Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - C.9.b) Implementation of changes which require additional minor assessment (e.g. change to the due date of obligations and conditions of a marketing authorisation and required pharmacovigilance activities in the risk management plan, including changes to the due date of study milestones, and template updates) - Accepted C.9.b (Type IB) – To update the RMP to remove the safety concern "Severe aplastic anaemia (Use in paediatric population)" from missing information, in line with the reference product (Revolade).				
Variation type IB / EMA/VR/0000324348	Outcome: C.9 Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - C.9.b) Implementation of changes which require additional minor assessment (e.g. change to the due date of obligations and conditions of a marketing authorisation and required pharmacovigilance activities in the risk management plan, including changes to the due date of study milestones, and template updates) - Accepted	25/02/2026			To update the RMP for Eltrombopag Accord 12.5/25/50/75 mg film coated tablets to include a safety concern for patients with hereditary fructose intolerance due to isomalt.

	C.9.b (Type IB) – To update the RMP for Eltrombopag Accord 12.5/25/50/75 mg film coated tablets to include a safety concern for patients with hereditary fructose intolerance due to isomalt.				
Variation type IA_IN / EMA/VR/0000317884	Outcome: B.II.b.1 Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - B.II.b.1.a Secondary packaging site - Accepted	17/12/2025			
Variation type IA_IN / EMA/VR/0000310271	Outcome: B.II.b.1 Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - B.II.b.1.a Secondary packaging site - Accepted	12/11/2025			
Variation type IB / EMA/VR/0000302834	Outcome: C.I HUMAN AND VETERINARY MEDICINAL PRODUCTS - C.I.z Implementation of QRD template - Accepted C.I.z (Type IB) – To update Sections 2 and 4.4 of the SmPC, Section 2 of the PL and Section 3 of the Labelling with a missing warning for the excipient isomalt (E953) in-line with the annex to the European Commission guideline on 'Excipients in the	10/10/2025	21/05/2026	SmPC, Labelling and PL	To update Sections 2 and 4.4 of the SmPC, Section 2 of the PL and Section 3 of the Labelling with a missing warning for the excipient isomalt (E953) in-line with the annex to the European Commission guideline on 'Excipients in the labelling and package leaflet of medicinal products for human use'.

	labelling and package leaflet of medicinal products for human use'.				
Variation type IB / EMA/VR/0000272976	Outcome: This was an application for a group of variations. B.II.e.5.a Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - B.II.e.5.a.2 Change outside the range of the currently approved pack sizes - Accepted B.II.e.5.a Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - B.II.e.5.a.2 Change outside the range of the currently approved pack sizes - Accepted B.II.e.5.a Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - B.II.e.5.a.2 Change outside the range of the currently approved pack sizes - Accepted B.II.e.5.a Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - B.II.e.5.a.2 Change outside the range of the currently approved pack sizes - Accepted	11/06/2025	21/05/2026	SmPC, Labelling and PL	
Variation type IA_IN / EMA/VR/0000272972	Outcome: This was an application for a group of variations. B.II.b.1 Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished	20/05/2025	21/05/2026	Annex II and PL	

	product - B.II.b.1.a Secondary packaging site - Accepted B.II.b.2.c Replacement or addition of a manufacturer responsible for importation and/or batch release - B.II.b.2.c.2 Including batch control/testing - Accepted				
Variation type IA_IN / EMA/VR/0000269269	Outcome: This was an application for a group of variations. B.II.e.5.a Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - B.II.e.5.a.1 Change within the range of the currently approved pack sizes - Accepted B.II.e.5.a Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - B.II.e.5.a.1 Change within the range of the currently approved pack sizes - Accepted B.II.e.5.a Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - B.II.e.5.a.1 Change within the range of the currently approved pack sizes - Accepted B.II.e.5.a Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - B.II.e.5.a.1 Change within the range of the currently approved pack sizes - Accepted B.II.e.5.a Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - B.II.e.5.a.1 Change within the range of the currently approved pack sizes - Accepted B.II.e.5.a Change in the number of units	12/05/2025	21/05/2026	SmPC, Labelling and PL	

	(e.g. tablets, ampoules, etc.) in a pack - B.II.e.5.a.1 Change within the range of the currently approved pack sizes - Accepted				