Veoza

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 IA_IN /	Q.II.f.1.b) Extension of the shelf life of the	21/04/2026		SmPC and PL	

[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/0000341632	finished product - Q.II.f.1.b.1 As packaged for sale (supported by real time data, fully in line with the stability protocol) - Accepted				
Variation type II / EMA/VR/0000287117	This was an application for a group of variations. B.I.b.1 Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - B.I.b.1.c Addition of a new specification parameter to the specification with its corresponding test method - Accepted B.I.a.1 Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - B.I.a.1.z Other variation - Accepted B.I.a.2 Changes in the manufacturing process of the active substance - B.I.a.2.a Minor change in the manufacturing process of the active substance - Accepted B.I.a.3 Change in batch size (including batch size ranges) of active substance or intermediate used in the manufacturing process of the active substance - B.I.a.3.a	15/01/2026			

	Up to 10-fold increase compared to the originally approved batch size - Accepted				
PSUR / EMA/PSUR/0000288230	Update of section 4.8 of the SmPC to remove information about incidence rates of ALT/AST elevations calculated from pooled data of clinical trials from the description of selected adverse reactions.	11/12/2025	12/02/2026	SmPC and PL	Update of section 4.8 of the SmPC to remove information about incidence rates of ALT/AST elevations calculated from pooled data of clinical trials from the description of selected adverse reactions.
Variation type IB / EMA/VR/0000307157	B.I.d.1.a Re-test period/storage period - B.I.d.1.a.4 Extension or introduction of a re-test period/storage period supported by real time data - Accepted	04/11/2025			
Variation type II / EMA/VR/0000255134	C.I.11 Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - C.I.11.b Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH where significant assessment by the competent authority is required* - Accepted Submission of an updated RMP version 4.2 in order to include Drug-Induced Liver Injury (DILI) as an important identified risk following PSUR procedure EMEA/H/C/PSUSA/00000231/202405	04/09/2025			

	(EMA/PRAC/544509/2024).				
Variation type IB / EMA/VR/0000255226	This was an application for a group of variations. B.II.f.1 Change in the shelf-life or storage conditions of the finished product - B.II.f.1.z Other variation - Accepted B.II.f.1.b Extension of the shelf life of the finished product - B.II.f.1.b.1 As packaged for sale (supported by real time data) - Accepted	21/03/2025	12/02/2026	SmPC	
PSUR / EMA/PSUR/0000248472					Based on the PRAC review of data on safety and efficacy, the PRAC considers that the risk-benefit balance of medicinal products containing fezolinetant remains unchanged and therefore recommends the maintenance of the marketing authorisation(s).