



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Velphoro

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 II /	C.I.3 Change(s) in the Summary of Product	12/02/2026		SmPC and PL	This variation procedure concerned an update of

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/0000315843	<p>Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - C.I.3.z Other variation - Accepted</p> <p>Update of section 4.5 of the SmPC in order to add drug-drug interaction information with vadadustat and roxadustat, following the outcome of procedure PSUSA/00010296/202411. The Patient Leaflet is updated accordingly.</p>				<p>section 4.5 of the SmPC and subsequently, section 2 of the Patient Leaflet in order to inform about drug-drug interaction information with vadadustat and roxadustat, following the outcome of procedure PSUSA/00010296/202411. The results of the in vitro and in vivo studies suggest that bioavailability of vadadustat and roxadustat may be reduced when taken concomitantly with phosphate binders such as Velphoro. Hence, vadadustat and roxadustat should be administered at least one hour before or two hours after Velphoro, to minimise the potential interactions. For more information, please refer to the Summary of Product Characteristics.</p>
PSUR / EMA/PSUR/0000257848					Maintenance