PHEBURANE

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:	29/05/2026		SmPC,	

[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/0000326657	C. Safety, efficacy, pharmacovigilance changes - C.z Other variation - Accepted C.z - (type IB) To update SmPC section 4.2 by adding "granules" for this pharmaceutical form and SmPC section 4.4 and labelling section 5, for the oral solution is amended by exchanging "medicine" for "flavour topping". The package leaflet was updated accordingly. SmPC section 6.6 is updated to include a warning about the viscosity of one of the flavor toppings. The package leaflet was updated accordingly. The MAH has also taken the opportunity to update the local representatives in BE, BG, CZ, DE, LU, HU, MT, NL, CY, EL, ES, AT, PL, PT, HR, IE, RO, SL, SV and IT.			Labelling and PL	
Variation type IB / EMA/VR/0000275735	Outcome: C.I HUMAN AND VETERINARY MEDICINAL PRODUCTS - C.I.z Other variation - Accepted To submit an experimentally derived n-octanol/water partition coefficient (log Kow) for sodium phenylbutyrate in an updated ERA.	20/06/2025			To submit an experimentally derived n-octanol/water partition coefficient (log Kow) for sodium phenylbutyrate in an updated ERA.
PSUR / EMA/PSUR/0000268988	EURD: PSUSA/00002758/202412 Active substance: sodium phenylbutyrate Outcome: Maintenance	04/09/2025			Maintenance