Versican Plus L4

Procedural steps taken and scientific information after the authorisation

Application number	Scope	Opinion / Notification [1] issued on	Commission Decision Issued [2] / amended on	Product Information affected [3]	Summary
IB/0009	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	17/04/2019		SPC, Annex II, Labelling and PL	The Agency accepted the variation to correct translation errors in the product information in several language versions (except English) following a quality defect.
R/0007	Renewal of the marketing authorisation.	21/02/2019	08/04/2019		The European Commission renewed the marketing authorisation for Versican Plus L4.
WS/1398	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. C.I.4.z - Change(s) in the SPC, Labelling or package leaflet further to a veterinary PSUR	13/09/2018	08/04/2019	SPC and PL	The Agency accepted the variation to update the SPC and package leaflet following PSUR assessment and to align the text to the latest QRD template.
WS/1337	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	13/09/2018	08/04/2019	SPC, Labelling and PL	The Agency accepted the worksharing procedure to use the products Versican Plus range during the second and third stages of pregnancy. However, safety of the products during the early stage of pregnancy and during lactation have not been investigated and this has been stated in the product information. The product information has been simultaneously aligned with the latest QRD template.

[1] Notifications are issued for type I variations (unless part of a group including a type II variation or higher procedure or a worksharing application). Opinions are issued for all other procedures.
[2] A CD is issued for procedures that affect the terms of the marketing authorisation (e.g. SPC, Annex II, Labelling, PL). The CD is issued within 2 months of the opinion for variations falling under the scope of Article 23.1a(a) of Regulation (EU) No. 712/2012, or within 1 year for other procedures.
[3] SPC (Summary of Product Characteristics), Annex II, Labelling, PL (Package Leaflet).

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000

					Annexes A of all products of the range have been updated.
IG/0951	C.I.9.b - Changes to an existing pharmacovigilance system as described in the DDPS - Change(s) in the safety database and/or major contractual arrangements for the fulfilment of PhV obligations, and/or change of the site undergoing PhV activities	05/07/2018	n/a		The Agency accepted the variation to update the current detailed description of the pharmacovigilance system (DDPS).
IG/0747	C.II.6.a - Changes to the labelling or the PL which are not connected with the SPC - Administrative information concerning the holder's representative	23/03/2017	28/09/2017	SPC, Labelling and PL	The Agency accepted the variation to update the list of local representatives in the product information.
WS/0959	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. C.I.4.z - Change(s) in the SPC, Labelling or package leaflet further to a veterinary PSUR	08/09/2016	28/09/2017	SPC and PL	The Agency accepted the worksharing procedure to update SPC and PL to implement the recommendation of a PSUR CVMP Assessment Report.
IG/0538	C.I.9.a - Changes to an existing pharmacovigilance system as described in the DDPS - Change in the QPPV and/or QPPV contact details and/or back-up procedure	01/04/2015	n/a		The Agency accepted the variation to change the QPPV.