14 September 2018
EMA/CVMP/574869/2018
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1] (post-authorisation)

Versican Plus DHPPi/L4R, Versican Plus DHPPi/L4, Versican Plus DHPPi, Versican Plus Pi/L4R, Versican Plus Pi/L4, Versican Plus Pi and Versican Plus L4.

Common name: Live, attenuated canine distemper, canine adenovirus, canine parvovirus and canine parainfluenza virus. Inactivated rabies virus and *Leptospira.*

On 13 September 2018, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a positive opinion[2], recommending the granting of a variation to the terms of the marketing authorisations for the veterinary medicinal products Versican Plus DHPPi/L4R, Versican Plus DHPPi/L4, Versican Plus DHPPi, Versican Plus Pi/L4R, Versican Plus Pi/L4, Versican Plus Pi and Versican Plus L4. The marketing authorisation holder for these veterinary medicinal products is Zoetis Belgium S.A.

Versican Plus DHPPi/L4R, Versican Plus DHPPi/L4, Versican Plus Pi/L4R, Versican Plus Pi/L4 and Versican Plus Pi are currently authorised as lyophilisate and suspension for suspension for injection. Versican Plus DHPPi and Versican Plus Pi are currently authorised as lyophilisate and solvent for suspension for injection. Versican Plus L4 is currently authorised as suspension for injection. The variation concerns the inclusion of data regarding the use of Versican Plus range vaccines during pregnancy. The variation introduces changes to the summary of product characteristics (SPC) and other product information. The product information has been simultaneously aligned with the latest quality review of documents (QRD) template v.8.1.

Detailed conditions for the use of these products are described in the updated summary of product characteristics (SPC), for which updated versions reflecting the changes will be published in the revised European public assessment reports (EPAR) and will be available in all official European Union languages after the variation to the marketing authorisations has been granted by the European Commission.

[1] Summaries of opinion are published without prejudice to the Commission Decision.
[2] Applicants may appeal any CVMP opinion, provided they notify the European Medicines Agency in writing of their intention to appeal within 15 days of receipt of the opinion.

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