6 June 2014
EMA/CVMP/301792/2014
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1] (initial authorisation)

Versican Plus L4

Common name: *Leptospira*.

On 5 June 2014, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a positive opinion[2], recommending the granting of a marketing authorisation for the veterinary medicinal product Versican Plus L4, a suspension for injection, intended for the active immunisation of dogs from six weeks of age

- to prevent clinical signs, infection and urinary excretion caused by *Leptospira* serovar Bratislava,
- to prevent clinical signs and urinary excretion and reduce infection caused by *Leptospira* serovars Canicola and Icterohaemorrhagiae,
- to prevent clinical signs and reduce infection and urinary excretion caused by *Leptospira* serovar Grippotyphosa.

The applicant for this veterinary product is Zoetis Belgium S.A.

The active substances of Versican Plus L4 are:

Leptospira interrogans serogroup Icterohaemorrhagiae serovar Icterohaemorrhagiae strain MSLB 1089	ARL* titre	≥ 1:51
Leptospira interrogans serogroup Canicola serovar Canicola, strain MSLB 1090	ARL* titre	≥ 1:51
Leptospira kirschneri serogroup Grippotyphosa serovar Grippotyphosa, strain MSLB 1091	ARL* titre	≥ 1:40
Leptospira interrogans serogroup Australis serovar Bratislava, strain MSLB 1088	ARL* titre	≥ 1:51

* Antibody micro agglutination-lytic reaction

The benefits of Versican Plus L4 are its prevention of leptospirosis.

The most common side effect is a transient swelling (up to 5 cm) at the injection site. Any such swelling will either have spontaneously resolved or be greatly diminished by 14 days after vaccination. In rare

[1] Summaries of opinion are published without prejudice to the Commission Decision, which will normally be issued within 90 days from adoption of the opinion.
[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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cases gastrointestinal signs such as diarrhoea and vomiting or anorexia and decreased activity are possible.

Detailed conditions for the use of this product will be described in the summary of product characteristics (SPC) which will be published in the European public assessment report (EPAR) and will be available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

The CVMP, on the basis of quality, safety and efficacy data submitted, considers that there is a favourable benefit to risk balance for Versican Plus L4 and therefore recommends the granting of the marketing authorisation.