

Versican Plus DHPPI/L4R (--) - Lyophilisate and suspension for suspension for injection

Authorised

- Canine parvovirus 2b, strain CPV-2b Bio 12/B, Live
- Canine parainfluenza virus 2, strain CPiV-2-Bio 15, Live
- Leptospira interrogans, serogroup Icterohaemorrhagiae, serovar Icterohaemorrhagiae, strain MSLB 1089, Inactivated
- Leptospira interrogans, serogroup Australis, serovar Bratislava, strain MSLB 1088, Inactivated
- Leptospira interrogans, serogroup Canicola, serovar Canicola, strain MSLB 1090, Inactivated
- Leptospira kirschneri, serogroup Grippotyphosa, serovar Grippotyphosa, strain MSLB 1091, Inactivated
- Rabies virus, strain SAD Vnukovo-32, Inactivated
- Canine distemper virus, strain CDV Bio 11/A, Live
- Canine adenovirus 2, strain CAV-2-Bio 13, Live

Product identification

Medicine name:

Versican Plus DHPPI/L4R (--) - Lyophilisate and suspension for suspension for injection

Active substance:

Canine parvovirus 2b, strain CPV-2b Bio 12/B, Live

Canine parainfluenza virus 2, strain CPiV-2-Bio 15, Live

Leptospira interrogans, serogroup Icterohaemorrhagiae, serovar Icterohaemorrhagiae, strain MSLB 1089, Inactivated

Leptospira interrogans, serogroup Australis, serovar Bratislava, strain MSLB 1088, Inactivated

Leptospira interrogans, serogroup Canicola, serovar Canicola, strain MSLB 1090, Inactivated

Leptospira kirschneri, serogroup Grippotyphosa, serovar Grippotyphosa, strain MSLB 1091, Inactivated

Rabies virus, strain SAD Vnukovo-32, Inactivated

Canine distemper virus, strain CDV Bio 11/A, Live

Canine adenovirus 2, strain CAV-2-Bio 13, Live

Target species:

Dog

Route of administration:

Subcutaneous use

Product details

Active substance and strength:

Canine parvovirus 2b, strain CPV-2b Bio 12/B, Live

Presentation_strength: $10^{4.3}$ - $10^{6.6}$ TCID₅₀ Reference:Ph Eur 0964

Comments:Lyophilisate Index:2

Canine parainfluenza virus 2, strain CPiV-2-Bio 15, Live

Presentation_strength: $10^{3.1}$ - $10^{5.1}$ TCID₅₀ Reference:Ph Eur 1955

Comments:Lyophilisate Index:3

Leptospira interrogans, serogroup Icterohaemorrhagiae, serovar Icterohaemorrhagiae, strain MSLB 1089, Inactivated

Presentation_strength:ALR titre $\geq$ 1:51 Reference:Ph Eur 0447 Comments:Suspension Index:4

Leptospira interrogans, serogroup Australis, serovar Bratislava, strain MSLB 1088, Inactivated

Presentation_strength:ALR titre $\geq$ 1:51 Reference:Ph Eur 0447 Comments:Suspension Index:5

Leptospira interrogans, serogroup Canicola, serovar Canicola, strain MSLB 1090, Inactivated

Presentation_strength:ALR titre $\geq$ 1:51 Reference:Ph Eur 0447 Comments:Suspension Index:6

Leptospira kirschneri, serogroup Grippotyphosa, serovar Grippotyphosa, strain MSLB 1091, Inactivated

Presentation_strength:ALR titre $\geq$ 1:40 Reference:Ph Eur 0447 Comments:Suspension Index:7

Rabies virus, strain SAD Vnukovo-32, Inactivated

Presentation_strength: $\geq$ 2.0 IU Reference:Ph Eur 0451 Comments:Suspension Index:8
Canine distemper virus, strain CDV Bio 11/A, Live

Presentation_strength: $10^{3.1}$ - $10^{5.1}$ TCID₅₀ Reference:Ph Eur 0448
Comments:Lyophilisate Index:0

Canine adenovirus 2, strain CAV-2-Bio 13, Live

Presentation_strength: $10^{3.6}$ - $10^{5.3}$ TCID₅₀ Reference:Ph Eur 1951
Comments:Lyophilisate Index:1

Pharmaceutical form:

Lyophilisate and suspension for suspension for injection

Withdrawal period by route of administration:**Subcutaneous use:**

- Dog

Anatomical therapeutic chemical veterinary (ATCvet) codes:

QI07AJ06

Legal status of supply:

Veterinary medicinal product subject to veterinary prescription

Authorisation status:

Valid

Authorised in:

Austria , Belgium , Bulgaria , Croatia , Cyprus , Czechia , Denmark , Estonia , Finland , France , Germany , Greece , Hungary , Iceland , Ireland , Italy , Latvia , Liechtenstein , Lithuania , Luxembourg , Malta , Netherlands , Norway , Poland , Portugal , Romania , Slovakia , Slovenia , Spain , Sweden , United Kingdom (Northern Ireland)

Package description:

Packaging:Lyophilisate: vial (glass); suspension: vial (glass),
Package_size:Lyophilisate: 50 vials + suspension: 50 vials, Content:Lyophilisate: 1
dose; suspension: 1 ml
Packaging:Lyophilisate: vial (glass); suspension: vial (glass),
Package_size:Lyophilisate: 25 vials + suspension: 25 vials, Content:Lyophilisate: 1
dose; suspension: 1 ml

Additional information

Entitlement type:

Marketing Authorisation

Legal basis of product authorisation:

Full application - New active substance (Article 12(3) of Directive No 2001/82/EC)

Marketing authorisation holder:

Zoetis Belgium SA

Marketing authorisation date:

7/05/2014

Manufacturing sites for batch release:

Bioveta a.s.

Responsible authority:

European Commission

Authorisation number:

This information is not available for this product.

Date of authorisation status change:

7/05/2014

To consult adverse reactions on veterinary medicinal products please go to
www.adrreports.eu/vet

Documents

Combined File of all Documents

English (PDF)

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