

RISPOVAL 2

Authorised

- Bovine parainfluenza virus 3, strain RLB103, Live
- ALUMINIUM HYDROXIDE GEL
- Bovine respiratory syncytial virus, strain 375, Live

Product identification

Medicine name:

RISPOVAL 2

Rispoval 2 / BRSV + Pi3 Lyofilisaat en oplosmiddel voor suspensie voor injectie voor runderen

Active substance:

Bovine parainfluenza virus 3, strain RLB103, Live

ALUMINIUM HYDROXIDE GEL

Bovine respiratory syncytial virus, strain 375, Live

Target species:

Cattle

Route of administration:

Intramuscular use

Product details

Active substance and strength:

Bovine parainfluenza virus 3, strain RLB103, Live

100000.00 log10 50% tissue culture infectious dose / 1.00 Dose

ALUMINIUM HYDROXIDE GEL

1.00 unit(s) / 1.00 Dose

Bovine respiratory syncytial virus, strain 375, Live

100000.00 log10 50% tissue culture infectious dose / 1.00 Dose

Pharmaceutical form:

Lyophilisate and solvent for suspension for injection

Withdrawal period by route of administration:

Intramuscular use:

-

Cattle

- All relevant tissues. 0 day

Anatomical therapeutic chemical veterinary (ATCvet) codes:

QI02AD07

Legal status of supply:

Veterinary medicinal product subject to veterinary prescription

Authorisation status:

Valid

Authorised in:

Netherlands

Available in:

Netherlands

Package description:

Cardboard box with 1 vial of lyophilisate (5 doses) and 1 vial of solvent (20 ml)

Cardboard box with 1 vial of lyophilisate (25 doses) and 1 vial of solvent (100 ml)

Additional information

Entitlement type:

Marketing Authorisation

Legal basis of product authorisation:

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

Marketing authorisation holder:

Zoetis B.V.

Marketing authorisation date:

25/01/2021

Manufacturing sites for batch release:

Zoetis Belgium

Responsible authority:

Medicines Evaluation Board

Authorisation number:

REG NL 125373

Date of authorisation status change:

29/06/2022

Reference member state:

France

Procedure number:

FR/V/0420/001

Concerned member states:

Belgium Croatia Czechia Estonia Germany Hungary Ireland Latvia Lithuania
Luxembourg Netherlands Portugal Slovakia Slovenia Spain
United Kingdom (Northern Ireland)

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

Documents

Combined File of all Documents

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