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Rispoval 2 / BRSV + Pi3 Lyophilisate and solvent for suspension for injection for cattle

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 Lyophilisate and solvent for suspension for injection for cattle

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:

Q102AD07

Legal status of supply:

Veterinary medicinal product not subject to veterinary prescription

Authorisation status:

Valid

Authorised in:

Ireland

Available in:

Ireland

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 Belgium S.A.

Marketing authorisation date:

19/02/2021

Manufacturing sites for batch release:

Zoetis Belgium

Responsible authority:

Health Products Regulatory Authority

Authorisation number:

VPA10387/100/001

Date of authorisation status change:

19/02/2021

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