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 Lyophilisat und Lösungsmittel zur Herstellung einer Injektionssuspension für Rinder

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:
Germany

Available in:
Germany

Package description:
Cardboard box with 1 vial of lyophilisate (25 doses) and 1 vial of solvent (100 ml)
Cardboard box with 1 vial of lyophilisate (5 doses) and 1 vial of solvent (20 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 Deutschland GmbH

Marketing authorisation date:
18/11/2020

Manufacturing sites for batch release:
Zoetis Belgium

Responsible authority:
Paul-Ehrlich-Institut

Authorisation number:
PEI.V.12018.01.1

Date of authorisation status change:
18/11/2020

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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