RISPOVAL 3 BRSV PI3 BVD LYOPHILISATE AND SUSPENSION FOR SUSPENSION FOR INJECTION FOR CATTLE

Not authorised

- Bovine viral diarrhoea virus 1, strain 6309, Inactivated
- Bovine respiratory syncytial virus, strain 375, Live
- Bovine parainfluenza virus 3, strain RLB103, Live
- Bovine viral diarrhoea virus 1, strain 5960, Inactivated

Product identification

Medicine name:
RISPOVAL 3 BRSV PI3 BVD LYOPHILISATE AND SUSPENSION FOR SUSPENSION FOR INJECTION FOR CATTLE

Active substance:
Bovine viral diarrhoea virus 1, strain 6309, Inactivated

Bovine respiratory syncytial virus, strain 375, Live

Bovine parainfluenza virus 3, strain RLB103, Live

Bovine viral diarrhoea virus 1, strain 5960, Inactivated

Target species:
Cattle

Route of administration:
Intramuscular use

Product details

Active substance and strength:

Bovine viral diarrhoea virus 1, strain 6309, Inactivated
3.00 log2 serum neutralising unit(s) / 1.00 Dose

Bovine respiratory syncytial virus, strain 375, Live
100000.00 50% cell culture infectious dose / 1.00 Dose

Bovine parainfluenza virus 3, strain RLB103, Live
100000.00 50% cell culture infectious dose / 1.00 Dose

Bovine viral diarrhoea virus 1, strain 5960, Inactivated
3.00 log2 serum neutralising unit(s) / 1.00 Dose

Pharmaceutical form:

Lyophilisate and suspension for suspension for injection

Withdrawal period by route of administration:

Intramuscular use:

- **Cattle**
  - All relevant tissues. no withdrawal period — Withdrawal period is 0 days

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Anatomical therapeutic chemical veterinary (ATCvet) codes:

QI02AH

Legal status of supply:

Veterinary medicinal product subject to veterinary prescription

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Authorisation status:

Surrendered

Authorised in:

Romania

Package description:

Cardboard box with 1 vial of lyophilised fraction (25 doses) and 1 vial of liquid fraction (100 ml)

Cardboard box with 1 vial of lyophilised fraction (5 doses) and 1 vial of liquid fraction (20 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

Marketing authorisation date:
3/05/2010

Manufacturing sites for batch release:
Zoetis Belgium

Responsible authority:
Institute For Control Of Biological Products And Veterinary Medicines

Authorisation number:
130194

Date of authorisation status change:
15/09/2016

Reference member state:
France

Procedure number:
FR/V/0146/001/MR

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

Documents

Summary of Product Characteristics

This document does not exist in this language (English). You can find it in another language below.