Bovalto Respi 4, Suspension for injection

Authorised

- Bovine viral diarrhoea virus, strain BIO-25, Inactivated
- Bovine respiratory syncytial virus, strain BIO-24, Inactivated
- Bovine parainfluenza virus 3, strain BIO-23, Inactivated
- Mannheimia haemolytica, serotype A1, strain DSM 5283, Inactivated

Product identification

Medicine name:
Bovalto Respi 4, Suspension for injection
Bovalto Respi 4

Active substance:
Bovine viral diarrhoea virus, strain BIO-25, Inactivated

Bovine respiratory syncytial virus, strain BIO-24, Inactivated

Bovine parainfluenza virus 3, strain BIO-23, Inactivated

Mannheimia haemolytica, serotype A1, strain DSM 5283, Inactivated

Target species:
Cattle

Route of administration:
Subcutaneous use

Product details

Active substance and strength:

Bovine viral diarrhoea virus, strain BIO-25, Inactivated
1.00 relative potency / 2.00 millilitre(s)

Bovine respiratory syncytial virus, strain BIO-24, Inactivated
1.00 relative potency / 2.00 millilitre(s)

Bovine parainfluenza virus 3, strain BIO-23, Inactivated
1.00 relative potency / 2.00 millilitre(s)

Mannheimia haemolytica, serotype A1, strain DSM 5283, Inactivated
1.00 relative potency / 2.00 millilitre(s)

Pharmaceutical form:

Suspension for injection

Withdrawal period by route of administration:

Subcutaneous use:

- **Cattle**
  - Milk. 0 hour
  - Meat and offal. 0 day

Anatomical therapeutic chemical veterinary (ATCvet) codes:

QI02AL

Legal status of supply:

Veterinary medicinal product subject to veterinary prescription

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Authorisation status:

Valid

Authorised in:

Germany

Available in:

Germany

Package description:
Plastic Vial 10 x 5.0 Dose
Glass Vial 10 x 5.0 Dose
Plastic Vial 1 x 50.0 Dose
Glass Vial 1 x 50.0 Dose
Plastic Vial 1 x 25.0 Dose
Glass Vial 1 x 25.0 Dose
Plastic Vial 1 x 5.0 Dose
Glass Vial 1 x 5.0 Dose
Plastic Vial 10 x 5.0 Dose
Glass Vial 10 x 5.0 Dose

Additional information

Entitlement type:
Marketing Authorisation

Legal basis of product authorisation:
Full application (Article 12(3) of Directive No 2001/82/EC)

Marketing authorisation holder:
Boehringer Ingelheim Vetmedica GmbH

Marketing authorisation date:
1/12/2015

Manufacturing sites for batch release:
Bioveta a.s.

Responsible authority:
Paul-Ehrlich-Institut

Authorisation number:
PEI.V.11802.01.1

Date of authorisation status change:
18/06/2020

Reference member state:
Czechia

Procedure number:
CZ/V/0129/001

Concerned member states:
Austria Belgium France Germany Greece Ireland Italy Luxembourg Malta Netherlands Poland Portugal Romania 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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