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

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:

Austria

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 Animal Health France

Marketing authorisation date:
10/12/2015

Manufacturing sites for batch release:
Bioveta a.s.

Responsible authority:
Austrian Agency For Health And Food Safety

Authorisation number:
836692

Date of authorisation status change:
10/12/2015

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

Summary of Product Characteristics

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

Labelling

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

Package Leaflet

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