Bovalto Respi 3, Suspension for injection

Authorised

- 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 3, Suspension for injection
Bovalto injeksjonsvæske, suspensjon

Active substance:
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 respiratory syncytial virus, strain BIO-24, Inactivated
1.00 relative potency / 1.00 Dose

Bovine parainfluenza virus 3, strain BIO-23, Inactivated
1.00 relative potency / 1.00 Dose

Mannheimia haemolytica, serotype A1, strain DSM 5283, Inactivated
1.00 relative potency / 1.00 Dose

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:

Norway

Available in:

Norway

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 Denmark A/S

Marketing authorisation date:
5/04/2016

Manufacturing sites for batch release:
Bioveta a.s.

Responsible authority:
Norwegian Medical Products Agency

Authorisation number:
15-10792

Date of authorisation status change:
29/05/2020

Reference member state:
Czechia

Procedure number:
CZ/V/0128/001

Concerned member states:
Austria Belgium Denmark France Germany Greece Ireland Italy Luxembourg Netherlands Norway Poland Portugal Romania Spain Sweden 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.

Package Leaflet

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