Bovalto Respi Intranasal, Nasal spray, lyophilisate and solvent for suspension

Authorised

- Bovine respiratory syncytial virus, strain BIO 24/A, Live
- Bovine parainfluenza virus 3, strain BIO 23/A, Live

Product identification

Medicine name:
Bovalto Respi Intranasal, Nasal spray, lyophilisate and solvent for suspension

Active substance:
Bovine respiratory syncytial virus, strain BIO 24/A, Live

Bovine parainfluenza virus 3, strain BIO 23/A, Live

Target species:
Cattle

Route of administration:
Nasal use

Product details

Active substance and strength:
Bovine respiratory syncytial virus, strain BIO 24/A, Live
7.50 log10 50% tissue culture infectious dose / 1.00 Dose

Bovine parainfluenza virus 3, strain BIO 23/A, Live
6.00 log10 50% tissue culture infectious dose / 1.00 Dose

Pharmaceutical form:
Nasal spray, lyophilisate and solvent for suspension

Withdrawal period by route of administration:
Nasal use:

- **Cattle**
  - Milk. 0 hour
  - Meat and offal. 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:
Glass Vial 1 x 5.0 Dose
Glass Vial 5 x 5.0 Dose
Glass Vial 1 x 10.0 Dose
Glass Vial 5 x 1.0 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:
19/03/2018

Manufacturing sites for batch release:
Bioveta a.s.

Responsible authority:
Paul-Ehrlich-Institut

Authorisation number:
PEI.V.11947.01.1

Date of authorisation status change:
2/06/2021

Reference member state:
Czechia

Procedure number:
CZ/V/0141/001

Concerned member states:
Austria Belgium Denmark France Germany Greece Ireland Italy Luxembourg Malta 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

Combined File of all Documents

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