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Bovilis INtranasal RSP Live nasal spray, lyophilisate and solvent for suspension for cattle

Authorised

- Bovine parainfluenza virus 3, strain INT2-2013, Live
- Bovine respiratory syncytial virus, strain Jencine-2013, Live

Product identification

Medicine name:
Bovilis INtranasal RSP Live nasal spray, lyophilisate and solvent for suspension for cattle
Bovilis INtranasal RSP Live vakcina A.U.V.

Active substance:
Bovine parainfluenza virus 3, strain INT2-2013, Live
Bovine respiratory syncytial virus, strain Jencine-2013, Live

Target species:
Cattle

Route of administration:
Nasal use

Product details

Active substance and strength:

Bovine parainfluenza virus 3, strain INT2-2013, Live
4.80 log10 50% tissue culture infectious dose / 2.00 millilitre(s)

Bovine respiratory syncytial virus, strain Jencine-2013, Live
5.00 log10 50% tissue culture infectious dose / 2.00 millilitre(s)

Pharmaceutical form:

Nasal spray, suspension

Withdrawal period by route of administration:

Nasal use:

- **Cattle**
  - Meat and offal. no withdrawal period zero days

Anatomical therapeutic chemical veterinary (ATCvet) codes:

QI02AD07

Legal status of supply:

Veterinary medicinal product subject to veterinary prescription

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Authorisation status:

Valid

Authorised in:

Hungary

Package description:

Cardboard box 5 x 5 doses of lyophilisate and 5 x 10 ml of solvent
Cardboard box with 20 doses of lyophilisate and cardboard box with 40 ml of solvent
Cardboard box with 1 dose of lyophilisate and 2 ml of solvent.
Cardboard box 5 x 1 dose of lyophilisate and 5 x 2 ml of solvent
Cardboard box 5 doses of lyophilisate and 10 ml of solvent.
Cardboard box 10 doses of lyophilisate and 20 ml of solvent.

Cardboard box with 10 doses of lyophilisate and cardboard box with 20 ml solvent
Cardboard box with 20 doses of lyophilisate and 40 ml of solvent

Additional information

Entitlement type:
Marketing Authorisation

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

Marketing authorisation holder:
Intervet International B.V.

Marketing authorisation date:
14/05/2019

Manufacturing sites for batch release:
Intervet International B.V.

Responsible authority:
Directorate Of Veterinary Medicinal Products

Authorisation number:
4063/X/19 NÉBIH ÁTI

Date of authorisation status change:
14/05/2019

Reference member state:
Netherlands

Procedure number:
NL/V/0257/001

Concerned member states:
Austria Belgium Bulgaria Croatia Cyprus Czechia Denmark Estonia Finland France Germany Greece Hungary Iceland Ireland Italy Latvia Lithuania Luxembourg Norway Poland Portugal Romania Slovakia Slovenia 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