SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose (2 ml) contains:

Active substances:
Live bovine respiratory syncytial virus (BRSV), strain Jencine-2013: 5.0 – 7.0 $\log_{10}$ $TCID_{50}$*
Live bovine parainfluenza virus type 3 (PI3), strain INT2-2013: 4.8 – 7.3 $\log_{10}$ $TCID_{50}$*

*50% tissue culture infective dose

Excipients:

Qualitative composition of excipients and other constituents
Lyophilisate:
Basal B8 medium
Hydrolysed gelatine
Pancreatic digest of casein
Sorbitol
Disodium hydrogen phosphate dihydrate
Solvent:
Disodium hydrogen phosphate dihydrate
Potassium dihydrogen phosphate
Sodium chloride
Sucrose
Water for injections

Lyophilisate: off-white or cream-coloured cake.
Solvent: clear colourless solution.

3. CLINICAL INFORMATION

3.1 Target species

Cattle.

3.2 Indications for use for each target species

For active immunisation of calves from the day of birth onwards to reduce clinical signs of respiratory disease and viral shedding from infection with BRSV and PI3.

Onset of immunity: BRSV: 6 days (for calves vaccinated from the day of birth onwards);
5 days (for calves vaccinated from the age of 1 week onwards);
PI3: 1 week.

Duration of immunity: 12 weeks.

3.3 Contraindications

None.

3.4 Special warnings

Vaccinate healthy animals only.

Animals should be preferably vaccinated at least 5 – 7 days before a period of stress or increased infection pressure.

The efficacy against BRSV may be reduced by presence of maternally derived antibodies.

3.5 Special precautions for use

Special precautions for safe use in the target species:
Vaccinated calves may excrete the vaccine strains up to 12 days following vaccination. It is recommended to vaccinate all calves of the herd.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Not applicable.

Special precautions for the protection of the environment:
Not applicable.

3.6 Adverse events

Cattle:

Very common (>1 animal / 10 animals treated):	Nasal discharge[1]. Elevated temperature[2].
Common (1 to 10 animals / 100 animals treated):	Cough[3], increased respiratory rate[4]. Ocular discharge[5].

[1] Mild and transient. Occurs during two days following vaccination.
[2] Minor and transient (very rarely up to 41.1 °C); normally resolves within four days.

[3] Mild and transient. Normally resolves in three days.
[4] Transient. Normally resolves within four days.
[5] Mild and transient. Normally resolves in two days.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:
Can be used during pregnancy.
The safety of the veterinary medicinal product has not been established during lactation.

3.8 Interaction with other medicinal products and other forms of interaction

Safety and efficacy data are available which demonstrate that this vaccine can be administered on the same day but not mixed with Bovilis Nasalgen-C. The vaccines should be given into different nostrils. The product information of that veterinary medicinal product should be consulted before administration.

No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product except the product mentioned above.
A decision to use this vaccine before or after any other veterinary medicinal product therefore needs to be made on a case by case basis.

3.9 Administration routes and dosage

Nasal use.

Calves can be vaccinated from the day of birth onwards.
Reconstitute lyophilisate with solvent as described below. Ensure that the lyophilisate is completely reconstituted before use. The reconstituted vaccine is an orange/brown to off-pink or pink coloured suspension.
Administer a single dose of 2 ml reconstituted vaccine per animal in one nostril.

Instructions for reconstitution:
1 and 5 dose presentations
For proper reconstitution of the lyophilisate, transfer the solvent to the vial with the lyophilisate (2 ml for the 1 dose, 10 ml for the 5 dose; also see the table below) using a needle and syringe. The vacuum in the vaccine vial will allow quick emptying of the syringe. Then resuspend by shaking. The vaccine suspension can be drawn up in a syringe with a clean tip. The vaccine in the syringe is now ready for administration, directly from the tip of the syringe. A spraying device is not required.

10 and 20 dose presentations
For proper reconstitution of the lyophilisate, transfer 10 ml of the solvent to the vial with the lyophilisate using a needle and syringe. The vacuum in the vaccine vial will allow quick emptying of the syringe. Then resuspend by shaking. Completely draw up the vaccine suspension and transfer it back to the solvent vial in order to get the correct

dose/volume ratio for the respective presentation (20 ml for the 10 dose, 40 ml for the 20 dose; also see the table below). The vaccine suspension can be drawn up in a syringe with a clean tip. The vaccine in the syringe is now ready for administration, directly from the tip of the syringe. A spraying device is not required.

When vaccinating animals, it is recommended to change syringes or tips of a multi-dose syringe between animals to avoid transmission of pathogens.

Doses per vial	Solvent volume required	dose volume
1	2 ml	2 ml
5	10 ml	2 ml
10	20 ml	2 ml
20	40 ml	2 ml

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

At a 10-fold maximum dose, no other signs than those described under section 3.6 have been observed. In individual calves exposed to very high maximum dosages (150-fold maximum dose) signs of moderate to severe respiratory disease have been observed.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Zero days.

4. IMMUNOLOGICAL INFORMATION

4.1 ATCvet code: QI02AD07.

The vaccine stimulates active immunity against bovine respiratory syncytial virus and bovine parainfluenza type 3 virus.

The vaccine stimulates receptors and cytokines involved in anti-viral innate immune responses.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product, except the solvent supplied for use with the veterinary medicinal product.

5.2 Shelf life

Shelf life of the lyophilisate as packaged for sale: 2 years.
Shelf life of the solvent as packaged for sale (2 ml): 3 years.
Shelf life of the solvent as packaged for sale (10 ml, 20 ml, 40 ml): 5 years.
Shelf life after reconstitution according to directions: 6 hours.

5.3 Special precautions for storage

Lyophilisate:
Store in a refrigerator (2 °C – 8 °C).
Do not freeze. Protect from light.

Solvent:
Store below 25 °C if stored independently from the lyophilisate.
Do not freeze.

5.4 Nature and composition of immediate packaging

Lyophilisate:
Type I glass vial of 1, 5, 10 or 20 doses closed with a halogenobutyl rubber stopper and aluminium cap.

Solvent:
Type I glass vial with 2 ml Unisolve and Type II glass vial with 10 ml, 20 ml or 40 ml Unisolve closed with a halogenobutyl rubber stopper and aluminium cap.

Pack sizes:
Cardboard box with:
- 1 dose of lyophilisate + 2 ml of solvent
- 5 doses of lyophilisate + 10 ml of solvent
- 10 doses of lyophilisate + 20 ml of solvent
- 20 doses of lyophilisate + 40 ml of solvent
- 5 x 1 dose of lyophilisate + 5 x 2 ml of solvent
- 5 x 5 doses of lyophilisate + 5 x 10 ml of solvent

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

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Intervet International B.V.

7. MARKETING AUTHORISATION NUMBER

Vm 06376/3025

8. DATE OF FIRST AUTHORISATION

20 June 2019

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

January 2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

Gavin Hall
Approved: 10 January 2025