**SUMMARY OF PRODUCT CHARACTERISTICS**

1. **NAME OF THE VETERINARY MEDICINAL PRODUCT**

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

AT, DE: Bovilis IntraNasal RSP Live

DK, NO: Bovilis RSP Live Vet

FI, SE: Bovilis RSP live vet

**2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

Each dose of 2 ml contains:

**Active substances:**

Live bovine respiratory syncytial virus (BRSV), strain Jencine-2013: 5.0 – 7.0 log10 TCID50\*

Live bovine parainfluenza virus type 3 (PI3), strain INT2-2013:4.8 – 6.5 log10 TCID50\*

\*50% tissue culture infective dose

**Excipients:**

For the full list of excipients, see section 6.1.

**3. PHARMACEUTICAL FORM**

Nasal spray, lyophilisate and solvent for suspension

Lyophilisate: off-white or cream-coloured cake.

Solvent: clear colourless solution.

**4. CLINICAL PARTICULARS**

**4.1 Target species**

Cattle

* 1. **Indications for use, specifying the target species**

For active immunisation of calves from the age of 1 week old onwards to reduce clinical signs of respiratory disease and viral shedding from infection with BRSV and PI3.

Onset of immunity: BRSV: 5 days

PI3: 1 week

Duration of immunity: 12 weeks

**4.3 Contraindications**

None.

**4.4 Special warnings for each target species**

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.

**4.5 Special precautions for use**

Special precautions for use in animals

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.

**4.6 Adverse reactions (frequency and seriousness)**

A mild and transient nasal discharge may very commonly occur during two days following vaccination. Mild and transient spontaneous coughing may commonly occur which normally resolves in three days. A mild and transient ocular discharge may commonly occur which normally resolves in two days. A transient rise in respiration rate may commonly occur which normally resolves within four days. A transient minor rise in body temperature may very commonly occur following vaccination (very rarely up to 41.1 °C) which normally resolves within four days.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals treated displaying adverse reaction(s))

- common (more than 1 but less than 10 animals in 100 animals treated)

- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)

- rare (more than 1 but less than 10 animals in 10,000 animals treated)

- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

**4.7 Use during pregnancy, lactation or lay**

Do not use during pregnancy and lactation.

**4.8 Interaction with other medicinal products and other forms of interaction**

No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product. 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.

**4.9 Amounts to be administered and administration route**

Nasal use.

Vaccinate calves of 1 week of age onwards.

Reconstitute lyophilisate with solvent as described below. Ensure that the lyophilisate is completely reconstituted before use. The reconstituted vaccine is an off-pink or pink coloured suspension.

Administer a single dose of 2 ml reconstituted vaccine per animal, 1 ml in each nostril.

Instructions for reconstitution:

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 and 20 ml for the 10 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.

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 |

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

At 10-fold overdose, no other signs than those described under section 4.6 have been observed. In individual calves exposed to very high vaccine dosages (150-fold maximum dose) signs of moderate to severe respiratory disease have been observed.

**4.11 Withdrawal period(s)**

Zero days.

**5. IMMUNOLOGICAL PROPERTIES**

Pharmacotherapeutic group: Immunologicals for bovidae, live viral vaccines

ATC vet 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.

**6. PHARMACEUTICAL PARTICULARS**

**6.1 List of excipients**

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

**6.2 Major incompatibilities**

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

**6.3 Shelf life**

Shelf life of the lyophilisate as packaged for sale: 18 months.

Shelf life of the solvent as packaged for sale: 5 years.

Shelf life after reconstitution according to directions: 6 hours.

**6.4 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.

**6.5 Nature and composition of immediate packaging**

Lyophilisate:

Type I glass vial of 1, 5, or 10 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 or 20 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

- 5 x 1 dose of lyophilisate + 5 x 2 ml of solvent

- 5 x 5 doses of lyophilisate + 5 x 10 ml of solvent

- 5 x 10 doses of lyophilisate + 5 x 20 ml of solvent

Not all pack sizes may be marketed.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

**7. MARKETING AUTHORISATION HOLDER**

Intervet UK Ltd.

Walton Manor

Walton

Milton Keynes

Buckinghamshire

MK7 7AJ

**8. MARKETING AUTHORISATION NUMBER**

Vm 01708/4612

**9. DATE OF FIRST AUTHORISATION**

20 June 2019

**10. DATE OF REVISION OF THE TEXT**

20 June 2019

Approved 20 June 2019

