SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rispoval RS+PI3 IntraNasal

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Per dose of 2 ml:

Powder
Active substance:
- Modified live Bovine Parainfluenza type 3 virus (PI3V), thermosensitive strain RLB103, $\geq 10^{5.0}$ and $\leq 10^{8.6}$ $CCID_{50}$*
- Modified live Bovine Respiratory Syncytial virus (BRSV) strain 375, $\geq 10^{5.0}$ and $\leq 10^{7.2}$ $CCID_{50}$*

*$CCID_{50}$: Cell Culture Infective Dose 50%

Diluent:
- Sodium chloride 18 mg
- Water for injection 2 ml

Excipients:
For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Powder and diluent for suspension for intranasal application. Slightly coloured powder and clear colourless diluent. The reconstituted, dissolved vaccine is a pinkish suspension.

4. CLINICAL PARTICULARS

4.1 Target Species

Cattle

4.2 Indications for Use, Specifying the Target Species

For active immunisation of maternally derived antibody positive or negative calves from 9 days of age against BRSV and PI3V, to reduce the mean titre and duration of excretion of both viruses.
Onset of protective immunity: 5 days for BRSV and 10 days for PI3V after a single vaccination.
Duration of protective immunity: 12 weeks following a single dose. The duration of protective immunity against the PI3V fraction may be reduced in MDA positive calves vaccinated before 3 weeks of age.

4.3 Contraindications

None.

4.4 Special warnings for Cattle

None.

4.5 Special precautions for use

Special precautions for use in animals

Vaccinate only healthy animals.
Vaccinal viruses can spread from vaccinated to non-vaccinated calves and may cause a serological response, but without causing clinical signs. In laboratory experiments based on the data using 3 week-old animals, shedding was observed for BRSV and PI3V up to 11 and 7 days respectively after vaccination with one dose containing the maximal virus content.
Animals should preferably be vaccinated at least 10 days before a period of stress or high infection risk like re-grouping or transport of animals, or at the start of the autumn season.
To achieve optimal results, it is recommended to vaccinate all the calves within the same herd.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

None

4.6 Adverse reactions (frequency and seriousness)

Published evidence shows that on rare occasions repeated exposure to RSV may trigger hypersensitivity reactions. In colostrum-deprived animals vaccinated before 3 weeks of age with a 10x overdose of vaccine, transient temperature increase, nutritional scour, abnormal faeces and demeanour were observed.

4.7 Use during pregnancy, lactation or lay

The safety and efficacy of the veterinary medicinal product has not been established during pregnancy and lactation. 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

Reconstitute the 1 dose and 5 dose presentations by aseptically adding all the liquid to the vial containing the powder components. Shake well before use.

Reconstitute the 25 dose presentation by mixing the lyophilised fraction with the solvent in 2 steps:

1. Inject 10 ml of the liquid fraction on the lyophilised plug in the freeze dried vial.
2. Shake well and extract the reconstituted lyophilised fraction from the freeze dried vial and mix with the liquid fraction in the liquid fraction vial.

Shake well before use.

Vaccination programme:
A single dose of 2 ml of reconstituted vaccine should be given intranasally using the intranasal applicators provided to cattle from the age of 9 days. It is recommended to change applicators between animals to avoid transmitting infectious organisms.

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

In colostrum-deprived animals vaccinated before 3 weeks of age with a 10x overdose of vaccine, transient temperature increase, nutritional scour, abnormal faeces and demeanour were observed.

4.11 Withdrawal Period(s)

Zero days

5. IMMUNOLOGICAL PROPERTIES

To stimulate active immunity against BRSV and PI3V.
ATC Vet code: QI02AD07 (immunologicals for bovidae, cattle, live viral vaccines, bovine Respiratory syncytial virus + bovine Parainfluenza virus).

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Powder:
- Buffered lactose solution
- Gelatin solution
- Casein hydrolysate solution
- HALS medium

6.2 Incompatibilities

Do not mix with any other veterinary medicinal product.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale (5 and 25 doses presentations): 2 years.
Shelf-life of the veterinary medicinal product as packaged for sale (1 dose presentation): 1 year.
Shelf-life after reconstitution according to directions: 2 hours.

6.4 Special Precautions for Storage

Store and transport refrigerated (2°C - 8°C). Do not freeze. Protect from light.

6.5 Nature and composition of immediate packaging

Cardboard box with 1 glass vial of 5 or 25 doses of powder accompanied by 1 vial containing respectively 10 or 50 ml liquid component. Both vials have rubber stopper and aluminium cap.
Plastic box with 5 glass vial(s) of 1 dose of powder accompanied by 5 vial(s) containing 2 ml liquid component. Both vials have rubber stopper and aluminium cap.
Nasal applicators for vaccination are also provided.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products, if appropriate

Dispose of waste material by boiling, incineration or immersion in an appropriate disinfectant approved for use by the competent authorities.

7. MARKETING AUTHORISATION HOLDER

Kernfarm B.V.,
De Corridor 14D,
3621 ZB Breukelen,
The Netherlands

8. MARKETING AUTHORISATION NUMBER

Vm 43877/4000

9. DATE OF THE FIRST AUTHORISATION

27 March 2015

10. DATE OF REVISION OF THE TEXT

May 2020

Approved: 27 May 2020