SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rispoval RS+PI3 IntraNasal nasal spray, lyophilisate and solvent for suspension for cattle

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 2 ml dose contains:

Active substances:

Lyophilisate
Bovine parainfluenza virus 3 (PI3V), strain RLB 103, live $10^{5.0}$ - $10^{8.6}$ $CCID_{50}$.
Bovine respiratory syncytial virus (BRSV), strain 375, live $10^{5.0}$ - $10^{7.2}$ $CCID_{50}$.

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

Excipients:

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Lyophilisate: slightly whitish to yellowish freeze-dried pellet.
Solvent: clear colourless liquid, free from visible impurities.

4. CLINICAL PARTICULARS

4.1 Target species

Cattle.

4.2 Indications for use, specifying the target species

For vaccination with Rispoval RS+PI3 IntraNasal only:
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 immunity: 5 days for BRSV and 10 days for PI3V after a single vaccination.
Duration of immunity: 12 weeks after a single vaccination. The duration of protective immunity against the PI3V fraction may be reduced in MDA positive calves vaccinated before 3 weeks of age.

For primary vaccination using Rispoval RS/Pi3 IntraNasal and booster vaccination with Rispoval 2/BRSV + Pi3*, refer to the Rispoval 2/BRSV Pi3* product information for specific details on indications.

* Where this veterinary medicinal product is authorised.

4.3 Contraindications

None.

4.4 Special warnings for each target species

Vaccinate healthy animals only.

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.

4.5 Special precautions for use

Special precautions for use in 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.

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.

Other precautions
Not applicable.

4.6 Adverse reactions (frequency and seriousness)

Cattle:

Rare (1 to 10 animals / 10,000 animals treated):	Hypersensitivity reaction (e.g. anaphylactic-type reaction)

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 the national competent authority via the national reporting system. See the package leaflet for respective contact details.

4.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:

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 Amount(s) to be administered and administration route

Dose: 2 ml.

Route: nasal use.

Reconstitution of the vaccine:

Reconstitute the 1 dose and 5 dose presentations by aseptically adding the solvent to the vial containing the lyophilisate. 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 solvent on the lyophilised plug in the vial containing the lyophilisate.
2. Shake well and extract the reconstituted lyophilised fraction from the vial and mix with the remaining solvent in the liquid fraction vial.

Shake well before use.

Reconstituted product: pink to orange liquid, which might contain a loose resuspendable sediment.

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

For primary vaccination using Rispoval RS/Pi3 IntraNasal and booster vaccination with Rispoval 2/BRSV + Pi3*, refer to the Rispoval 2/BRSV Pi3* product information for specific details on vaccination programme.

* Where this veterinary medicinal product is authorised.

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

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

4.11 Withdrawal period(s)

Zero days.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: immunologicals for bovidae, cattle, live viral vaccines, bovine Respiratory syncytial virus + bovine Parainfluenza virus.

ATCvet code: QI02AD07

To stimulate active immunity against BRSV and PI3V.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lyophilisate:
Buffered lactose solution
Gelatin solution
Casein hydrolysate solution
HALS medium

Solvent:
Sodium chloride
Water for injections

6.2 Major incompatibilities

Do not mix with any other veterinary medicinal product, except solvent supplied for use with the 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 lyophilisate accompanied by 1 glass vial containing respectively 10 or 50 ml of solvent. Both vials have rubber stopper and aluminium cap.

Plastic box with 5 glass vial(s) of 1 dose of lyophilisate accompanied by 5 glass vial(s) containing 2 ml of solvent. Both vials have rubber stopper and aluminium cap.

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

Medicines should not be disposed of via wastewater.

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

Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

8. MARKETING AUTHORISATION NUMBER

Vm 42058/5145

9. DATE OF FIRST AUTHORISATION

11 October 2005

10. DATE OF REVISION OF THE TEXT

September 2024

PROHIBITION OF SALE, SUPPLY AND/OR USE
Not applicable.

11. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Find more product information by searching for the ‘Product Information Database’ or ‘PID’ on www.gov.uk.

Gavin Hall

Approved 01 October 2024