ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARDBOARD BOX (5 OR 25 DOSES)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE SUBSTANCES

Each 2 ml dose contains:

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 $10^{5.0}$ - $10^{7.2}$ $CCID_{50}$.

3. PACKAGE SIZE

1 x 5 doses
1 x 25 doses

4. TARGET SPECIES

Cattle

5. INDICATIONS

To be completed nationally.
<For products not subject to veterinary prescription.>

6. ROUTES OF ADMINISTRATION

Nasal use.

7. WITHDRAWAL PERIODS

Withdrawal period: Zero days.

8. EXPIRY DATE

Exp. {mm/yyyy}
Once reconstituted use within 2 hours.

9. SPECIAL STORAGE PRECAUTIONS

Store and transport refrigerated.
Do not freeze.
Protect from light.

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Zoetis UK Limited

14. MARKETING AUTHORISATION NUMBERS

Vm 42058/3038

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

PLASTIC BOX (1 DOSE)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE SUBSTANCES

Each 2 ml dose contains:

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 $10^{5.0}$ - $10^{7.2}$ $CCID_{50}$.

3. PACKAGE SIZE

5 x 1 dose

4. TARGET SPECIES

Cattle

5. INDICATIONS

To be completed nationally.
<For products not subject to veterinary prescription.>

6. ROUTES OF ADMINISTRATION

Nasal use.

7. WITHDRAWAL PERIODS

Withdrawal period: Zero days.

8. EXPIRY DATE

Exp. {mm/yyyy}
Once reconstituted use within 2 hours.

9. SPECIAL STORAGE PRECAUTIONS

Store and transport refrigerated.
Do not freeze.
Protect from light.

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Zoetis UK Limited

14. MARKETING AUTHORISATION NUMBERS

Vm 42058/3038

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

LABEL ON GLASS VIAL – LYOPHILISATE (5 OR 25 DOSES)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE SUBSTANCES

PI3V, strain RLB 103, live $10^{5.0}$ - $10^{8.6}$ $CCID_{50}$.
BRSV, strain 375, live $10^{5.0}$ - $10^{7.2}$ $CCID_{50}$.

5 doses
25 doses

3. TARGET SPECIES

Cattle

4. ROUTES OF ADMINISTRATION

Nasal use.
Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal period: Zero days.

6. EXPIRY DATE

Exp. {mm/yyyy}
Once reconstituted use within 2 hours.

7. SPECIAL STORAGE PRECAUTIONS

Store and transport refrigerated.
Do not freeze.
Protect from light.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Zoetis UK Limited

9. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

LABEL ON GLASS VIAL – LYOPHILISATE (1 DOSE)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rispoval RS+PI3 IntraNasal

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Live BRSV, and bovine PI3V

1 dose

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}
Once reconstituted use within 2 hours.

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

LABEL ON GLASS VIAL – SOLVENT (2, 10 OR 50 ML)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rispoval RS+PI3 IntraNasal solvent

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

1 dose (2 ml)
5 doses (10 ml)
25 doses (50 ml)

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}
Once reconstituted use within 2 hours.

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

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

2. 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%.

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

3. Target species

Cattle.

4. Indications for use

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.

5. Contraindications

None.

6. Special warnings

Special warnings:
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.

Special precautions for safe use in the target species:
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.

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.

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.

Overdose:
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.

Special restrictions for use and special conditions for use:
To be completed nationally.

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

7. Adverse events

Cattle:

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

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder <or the local representative of the marketing authorisation holder> using the contact details at the end of this leaflet, or via your national reporting system: {national system details}.

8. Dosage for each species, routes and method of administration

Dose: 2 ml.

Route: nasal use.

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.

9. Advice on correct administration

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 lyophilized 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.

10. Withdrawal periods

Zero days.

11. Special storage precautions

Keep out of the sight and reach of children.

Store and transport refrigerated (2 °C - 8 °C).
Do not freeze.
Protect from light.
Do not use this veterinary medicinal product after the expiry date which is stated on the label and carton after Exp. The expiry date refers to the last day of that month.
Shelf life after reconstitution according to directions: use within 2 hours.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater <or household waste>.

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 applicable national collection systems. These measures should help to protect the environment.

Ask your <veterinary surgeon> <or> <pharmacist> how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

AT, BE, BG, CZ, DE, EE, ES, FR, HU, IT, LT, LU, LV, NL, PL, PT, RO, SK, UK(NI):
Veterinary medicinal product subject to prescription.
IE: Veterinary medicinal product not subject to prescription.

14. Marketing authorisation numbers and pack sizes

Vm 42058/3038

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.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

16. Contact details

Marketing authorisation holder <and contact details to report suspected adverse reactions>:
Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

Manufacturer responsible for batch release:
Zoetis Belgium
Rue Laid Burniat 1
1348 Louvain-La-Neuve
Belgium

<Local representatives <and contact details to report suspected adverse reactions>:>
To be completed nationally (if needed).

17. Other information

To stimulate active immunity against BRSV and PI3V.

Gavin Hall

Approved 01 October 2024