

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE - CARDBOARD BOX (5
OR 25 DOSES)**

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rispoval 2 / BRSV + Pi3 lyophilisate and solvent for suspension for injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each 4 ml dose contains:

Bovine parainfluenza virus 3 (Pi3V), strain RLB 103, live $10^{5.0} - 10^{8.6}$ CCID₅₀.
Bovine respiratory syncytial virus (BRSV), strain 375, live $10^{5.0} - 10^{7.2}$ CCID₅₀.

3. PACKAGE SIZE

5 doses
25 doses

4. TARGET SPECIES

Cattle

5. INDICATION(S)

6. ROUTES OF ADMINISTRATION

Intramuscular use.

7. WITHDRAWAL PERIODS

Withdrawal period: Zero days.

8. EXPIRY DATE

Exp. {mm/yyyy}
Once reconstituted use immediately.

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 42058/5144

15. BATCH NUMBER

Lot {number}

16. SPECIAL WARNING(S), IF NECESSARY

17. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: Read package leaflet.

18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

POM-V Veterinary medicinal product subject to prescription

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING
UNITS LABEL ON GLASS VIAL – LYOPHILISATE (5 OR 25 DOSES)**

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rispoval 2 / BRSV + Pi3



**2. QUALITATIVE AND QUANTITATIVE PARTICULARS OF THE ACTIVE
SUBSTANCE(S)**

Live bovine Pi3V and BRSV

5 doses

25 doses

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

Once reconstituted use immediately.

5. ROUTE(S) OF ADMINISTRATION

IM

6. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING
UNITS LABEL ON GLASS VIAL – SOLVENT (20 OR 100 ml)**

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rispoval 2 / BRSV + Pi3



**2. QUALITATIVE AND QUANTITATIVE PARTICULARS OF THE ACTIVE
SUBSTANCE(S)**

5 doses (20 ml)
25 doses (100 ml)

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}
Once reconstituted use immediately.

5. ROUTE(S) OF ADMINISTRATION

IM

6. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rispoval 2 / BRSV + Pi3 lyophilisate and solvent for suspension for injection for cattle

2. COMPOSITION

Each 4 ml dose contains:

Active substances:

Lyophilisate

Bovine parainfluenza virus 3 (Pi3V), strain RLB 103, live $10^{5.0} - 10^{8.6}$ CCID₅₀.

Bovine respiratory syncytial virus (BRSV), strain 375, live $10^{5.0} - 10^{7.2}$ CCID₅₀.

CCID₅₀ = Cell Culture Infectious Dose 50%.

Adjuvant:

Aluminium hydroxide gel 0.8 ml (equivalent to 24.36 mg of aluminium hydroxide).

Lyophilisate: slightly whitish to yellowish freeze-dried pellet.

Solvent: pinkish to orange-brown turbid liquid, which might contain loose sediment. On shaking well, the sediment is easily resuspended.

3. TARGET SPECIES

Cattle.

4. INDICATIONS FOR USE

For vaccination with Rispoval 2 only:

Active immunisation of cattle from 12 weeks of age to:

- reduce virus excretion caused by bovine Pi3V and
- reduce virus excretion caused by BRSV infection.

Onset of immunity: 3 weeks after the basic vaccination scheme.

Duration of immunity: 6 months after the basic vaccination scheme for BRSV.

Duration of immunity has not been established for bovine Pi3V.

For active immunisation with Rispoval RS+Pi3 IntraNasal* as basic vaccination and Rispoval 2 as booster vaccination from 13 weeks of age to:

- reduce the virus excretion caused by bovine Pi3V and BRSV infection and
- reduce the clinical signs (cough, depression, dyspnea, increased respiratory rate, elevated rectal temperature) associated with BRSV infection.

Onset of Immunity: 3 weeks after the booster vaccination.
Duration of Immunity: 6 months for BRSV and 3 months for Pi3V after the booster vaccination.

* Where this veterinary medicinal product is authorised.

5. CONTRAINDICATIONS

None.

6. SPECIAL WARNINGS

Special warnings:

Vaccinate healthy animals only.

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

In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

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:

Reactions after administration of an overdose of vaccine are not different from those after the single dose.

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:

Very common (>1 animal / 10 animals treated):
Hyperthermia ¹
Injection site inflammation ²
Very rare (<1 animal / 10,000 animals treated, including isolated reports):
Hypersensitivity reaction [e.g. anaphylactic-type reaction (severe allergic reaction)] ³

¹Transient and mild; can last for 2 days.

²Transient and minor; up to 0.5 cm which disappears within 15 days.

³In case of anaphylactic reaction, symptomatic treatment should be provided.

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 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: 4 ml.

Route: intramuscular use.

Vaccination scheme:

For vaccination with Rispoval 2 only:

Basic vaccination: two doses 3-4 weeks apart from 12 weeks of age.

Re-vaccination: if continued protection against BRSV is required, then animals should be revaccinated with two doses after 6 months. The duration of immunity of the Pi3V component is not known.

For use as a booster vaccination after basic vaccination with Rispoval RS+Pi3

IntraNasal*:

A single dose of Rispoval 2 three months after the basic vaccination with Rispoval RS+Pi3 IntraNasal*.

If continued protection against BRSV is required, then animals should be revaccinated with a single dose after 6 months. If continued protection against Pi3V is required, then animals should be revaccinated with a single dose after 3 months.

* Where this veterinary medicinal product is authorised.

Animals should preferably be vaccinated at least 3 weeks before a period of stress or high infection risk such as re-grouping or transport of animals, or the start of autumn season.

9. ADVICE ON CORRECT ADMINISTRATION

Reconstitution of the vaccine:

Reconstitute the vaccine by adding the solvent to the vial containing the lyophilisate.

When the lyophilisate and solvent are filled in equally sized vials, inject the entire solvent into the vial containing the lyophilisate.

When the lyophilisate is filled in a smaller vial size than the solvent, the reconstitution of the vaccine is carried out 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-orange turbid suspension with loose 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 immediately

12. SPECIAL PRECAUTIONS FOR DISPOSAL

Medicines should not be disposed of via wastewater.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required. These measures should help to protect the environment.

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

13. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 42058/5144

Cardboard box with 1 glass vial of lyophilisate (5 doses) and 1 glass vial of solvent (20 ml). Both vials have rubber stopper and aluminium cap.

Cardboard box with 1 glass vial of lyophilisate (25 doses) and 1 glass vial of solvent (100 ml). 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
Tel: +44 (0) 345 300 8034

Manufacturer responsible for batch release:

Zoetis Belgium
Rue Laid Burniat 1
1348 Louvain-La-Neuve
Belgium

17. OTHER INFORMATION

To stimulate an active immunity against Pi3V and BRSV.

For animal treatment only.

Gavin Hall

Approved 01 October 2024