

PARTICULARS TO APPEAR ON THE OUTER PACKAGE
Outer Carton
1 x 25 ml (5 doses)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rispoval 4 lyophilisate and suspension for suspension for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each 5 ml dose contains:

Active substances:

Suspension:

Infectious Bovine Rhinotracheitis (IBR) virus	\geq GMT 2 log ₂ *
Bovine Viral Diarrhoea (BVD) virus	\geq GMT 5 log ₂ *

* GMT Serological titre induced after injection to calves.

Lyophilisate:

Bovine Parainfluenza 3 (PI3) virus	> or equal 10 ^{5.0} CCID ₅₀
Bovine Respiratory Syncytial Virus (BRSV)	> or equal 10 ^{5.0} CCID ₅₀

3. PACKAGE SIZE

1 x 5 dose lyophilisate
1 x 5 dose suspension (25 ml)

4. TARGET SPECIES

Cattle.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Intramuscular use.

7. WITHDRAWAL PERIODS

Zero days.

8. EXPIRY DATE

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

9. SPECIAL STORAGE PRECAUTIONS

Store and transport refrigerated (2 °C – 8 °C).
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 42058/5171

15. BATCH NUMBER

Lot {number}

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING
UNITS**

Lyophilisate vial label
5 doses

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rispoval 4

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Lyophilisate containing BRSV, $\geq 10^{5.0}$ CCID₅₀, and PI3 virus, $\geq 10^{5.0}$ CCID₅₀.
Only to be mixed with the suspension fraction of Rispoval 4.

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
Solvent vial label
5 doses

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rispoval 4

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Suspension containing IBR virus, \geq GMT $2\log_2$, and BVD virus, \geq GMT $5\log_2$.
Only to be mixed with the lyophilisate fraction of Rispoval 4.

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

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

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Rispoval 4 lyophilisate and suspension for suspension for injection

2. Composition

Each 5 ml dose contains:

Active substances:

Suspension fraction:

Infectious Bovine Rhinotracheitis (IBR) virus, strain Cooper, \geq GMT 2 log₂*

Bovine Viral Diarrhoea (BVD) virus, cytopathic strain 5960
and Bovine Viral Diarrhoea (BVD) virus, non-cytopathic strain 6309, \geq GMT 5 log₂*

* GMT Serological titre induced after injection to calves.

Lyophilisate fraction:

Bovine Parainfluenza 3 (PI3) virus, thermosensitive strain RLB103,
minimum titre at the end of shelf life, $>$ or equal 10^{5.0} CCID₅₀

Bovine Respiratory Syncytial Virus (BRSV) strain 375,
minimum titre at the end of shelf life, $>$ or equal 10^{5.0} CCID₅₀

Adjuvant:

Aluminium hydroxide (2 % Al₂O₃) \leq 5.2 mg Al₂O₃ per ml

Liquid fraction:

Slightly coloured turbid liquid, which might contain loose sediment. On shaking well, the sediment is easily resuspended.

Freeze-dried fraction:

Slightly coloured freeze-dried pellet.

3. Target species

Cattle.

4. Indications for use

For active immunisation of cattle to reduce infection, clinical signs and respiratory disease caused by Bovine Respiratory Syncytial virus (BRSV), Infectious Bovine Rhinotracheitis (IBR, commonly known as BHV-1) virus and Parainfluenza virus type 3 (PI3); and leukopenia and viraemia caused by the Bovine Viral Diarrhoea (BVD) virus Type I, cytopathic and non-cytopathic strains.

5. Contraindications

None.

6. Special warnings

Special warnings:

Vaccinate healthy animals only.

Pregnancy:

Do not use during the whole pregnancy.

Interaction with other medicinal products and other forms of interaction:

Safety and efficacy data are available which demonstrate that this vaccine can be administered on the same day but not mixed with Rispoval Pasteurella.

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

Major incompatibilities:

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

7. Adverse events

Cattle:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Injection site reaction ¹
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¹ Mild, transient. Up to 0.5 cm and completely resolved within 15 days.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal 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 at:

Website: <https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine>

e-mail: adverse.events@vmd.gov.uk

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

DOSE: 5 ml

ROUTE: Intramuscular use.

Reconstitute the vaccine by adding the liquid to the vial containing the powder component.

When the lyophilised fraction and liquid fraction are filled in equally sized vials: Inject the entire liquid fraction into the freeze-dried vial.

When the lyophilised fraction is filled in a smaller vial size than the liquid fraction, the reconstitution of the vaccine is carried out in 2 steps:
Inject 10ml of the liquid fraction on the lyophilised plug in the freeze-dried vial.
Shake well and extract the reconstituted lyophilised fraction from the freeze-dried vial and mix with the liquid fraction in the liquid fraction vial.

VACCINATION PROGRAMME:

For cattle over 3 months of age:

Two doses of 5 ml of reconstituted vaccine should be given three to four weeks apart to cattle.

Ideally, calves should be vaccinated at least 2 weeks before transport, mixing of animals of different origins, housing, or any other event which may cause the animals to be stressed or exposed to new infections. Calves are usually most susceptible during early autumn. The vaccine will protect animals against BRSV, PI3, IBR and BVD for at least 6 months, which will cover the period of risk from respiratory infections.

Should cattle be at risk from these respiratory diseases at a subsequent time, the same vaccination scheme is recommended at least 14 days prior to the period of expected disease challenge.

For cattle over 3 weeks of age:

For cattle from 3 weeks of age, vaccination leads to seroconversion of seronegative calves vaccinated at 3 and 6 weeks of age. The influence of maternally derived antibodies has not been studied in detail and it is therefore recommended that calves vaccinated before 12 weeks of age are re-vaccinated at 12 weeks of age.

9. Advice on correct administration

Shake well before use.

Reconstituted product: pink to orange turbid 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. The expiry date refers to the last day of that month.

Shelf life after reconstitution according to directions: 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 how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 42058/5171

Cardboard carton containing a 5 dose vial of lyophilisate, supplied with a vial containing 25 ml (5 doses) of suspension.

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

POM-V

Gavin Hall

Approved: 06 November 2025