

PARTICULARS TO APPEAR ON THE OUTER PACKAGE
Cardboard box containing lyophilisate vial of 5, 10, 25 or 50 doses and solvent
vial of 10, 20, 50 or 100 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rispoval Pasteurella lyophilisate and solvent for emulsion for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each 2 ml dose contains:

Active substances:

Mannheimia haemolytica serotype A1, strain NL 1009, leukotoxoid 200 – 2,196 RU*

Mannheimia haemolytica serotype A1, strain NL 1009, capsular antigens 345 –10,208 RU*

* ELISA relative units.

3. PACKAGE SIZE

5 dose lyophilisate x 10 ml solvent vial

10 dose lyophilisate x 20 ml solvent vial

25 dose lyophilisate x 50 ml solvent vial

50 dose lyophilisate x 100 ml solvent vial

4. TARGET SPECIES

Cattle.

5. INDICATIONS

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 in a refrigerator.

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 Belgium S.A.

14. MARKETING AUTHORISATION NUMBERS

Vm 60021/3019

15. BATCH NUMBER

Lot {number}

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

Lyophilisate Vial
5 doses, 10 doses, 25 doses, 50 doses

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rispoval Pasteurella

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Each 2 ml dose contains:

Lyophilisate containing inactivated leukotoxoid (between 200 and 2,196 RU*) and capsular antigens (between 345 and 10,208 RU*) of *Mannheimia haemolytica* biotype A, serotype 1.

* ELISA relative units.

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

Once reconstituted use immediately.

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING
UNITS
Emulsion Vial
5 doses, 10 doses, 25 doses, 50 doses

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rispoval Pasteurella

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Emulsion containing aluminium hydroxide and liquid paraffin as adjuvant.

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Risposal Pasteurella lyophilisate and solvent for emulsion for injection

2. Composition

Each 2 ml dose contains:

Active substances:

Lyophilised fraction:

Mannheimia haemolytica serotype A1, strain NL 1009, leukotoxoid 200 – 2,196 RU*

Mannheimia haemolytica serotype A1, strain NL 1009, capsular antigens 345 – 10,208 RU*

* ELISA relative units.

Adjuvants:

Liquid fraction:

Amphigen base** (liquid paraffin + soya lecithin) 0.025 ml

Liquid paraffin 0.075 ml

Aluminium (Al³⁺) 2.58 mg

** In Amphigen base 60% (0.016 ml) is liquid paraffin.

Freeze-dried fraction: whitish powder.

Liquid fraction: milk-like liquid which might show some creaming, which disappears on shaking well.

3. Target species

Cattle.

4. Indications for use

For active immunisation of cattle to reduce lesions and respiratory disease caused by *Mannheimia haemolytica* biotype A, serotype 1.

Onset of immunity: 7 days.

Duration of immunity: 17 weeks.

5. Contraindications

None.

6. Special warnings

Special warnings:

Vaccinate healthy animals only.

Special precautions for safe use in the target species:

Calves should be vaccinated at least 7 days 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 for at least 17 weeks, which will cover the period of risk from pasteurellosis.

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

Ensure that the method of restraint, handling, and administration, e.g. by the use of guarded needles, minimises the risk of accidental injection/self-injection.

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

To the user:

This veterinary medicinal product contains mineral oil. Accidental injection/self-injection may result in severe pain and swelling, particularly if injected into a joint or finger, and in rare cases could result in the loss of the affected finger if prompt medical attention is not given. If you are accidentally injected with this veterinary medicinal product, seek prompt medical advice even if only a very small amount is injected and take the package leaflet with you. If pain persists for more than 12 hours after medical examination, seek medical advice again.

To the physician:

This veterinary medicinal product contains mineral oil. Even if small amounts have been injected, accidental injection with this veterinary medicinal product can cause intense swelling, which may, for example, result in ischaemic necrosis and even the loss of a digit. Expert, PROMPT, surgical attention is required and may necessitate early incision and irrigation of the injected area, especially where there is involvement of finger pulp or tendon.

Pregnancy:

Do not use during the whole pregnancy.

Fertility:

Do not use in heifers at the time of breeding.

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 RS.

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 emulsion supplied with the product.

7. Adverse events

Cattle:

Very common (>1 animal / 10 animals treated):	Local swelling at the injection ^{1,2} Elevated temperature ³
Rare (1 to 10 animals / 10 000 animals treated):	Hypersensitivity reactions ⁴
Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Muscle tremor

¹ Local, up to 14 cm in diameter, soft, no painful.

² Mild, transient, and completely resolved within 15 days or up to 52 days on rare occasions.

³ Transient. Up to 4 hours following dosing up to a maximum of 40.9 °C.

⁴ Appropriate treatment e.g. adrenaline and/or antihistamine should be given without delay.

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 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

Vaccination programme:

A single two ml dose of reconstituted vaccine to be given via intramuscular injection to healthy cattle over the age of 3 months.

Should cattle be at risk from pasteurellosis at a subsequent time, a single vaccination is recommended at least 7 days prior to the period of expected disease challenge.

9. Advice on correct administration

Reconstitute the vaccine by first shaking the vial containing the emulsion, and then aseptically withdraw and add all the emulsion to the vial containing the lyophilisate. Shake well.

Do not use chemically sterilised syringes or needles.

10. Withdrawal periods

Zero days.

11. Special storage precautions

Keep out of the sight and reach of children.

Store in a refrigerator (2 °C – 8 °C).

Do not freeze.

Protect from light.

Do not use this veterinary medicinal product after 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: use immediately.

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 60021/3019

Pack containing a 5, 10, 25, or 50 dose vial of lyophilisate together with a vial of emulsion containing 10, 20, 50, or 100 ml.

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 events:

Zoetis Belgium S.A.
2nd Floor, Building 10
Cherrywood Business Park
Loughlinstown
Dublin 18
D18 T3Y1
Ireland
Tel: +353 (0) 1 256 9800

Manufacturer responsible for batch release:

Zoetis Belgium S.A.
Rue Laid Burniat 1
1348 Louvain-la-Neuve
Belgium

17. Other information

POM-V

Gavin Hall
Approved: 12 December 2025