

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rispoval Pasteurella lyophilisate and solvent for emulsion for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 2 ml dose contains:

Active substances:

Lyophilised fraction:

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

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

* ELISA relative units.

Liquid fraction:

Adjuvants:

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.

Excipients:

Qualitative composition of excipients and other constituents

Lyophilised fraction:

Phosphate buffered saline

Liquid fraction:

Polysorbate 80

Sorbitan oleate

Phosphate buffered saline

Freeze-dried fraction: whitish powder.

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

3. CLINICAL INFORMATION

3.1 Target species

Cattle.

3.2 Indications for use for each target species

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.

3.3 Contraindications

None.

3.4 Special warnings

Vaccinate healthy animals only.

3.5 Special precautions for use

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.

Special precautions for the protection of the environment:
Not applicable.

3.6 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 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.

3.7 Use during pregnancy, lactation or lay

Pregnancy:

Do not use during the whole pregnancy.

Fertility:

Do not use in breeding animals.

3.8 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.

3.9 Administration routes and dosage

Intramuscular use.

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 and aseptically administer 2 ml intramuscularly. Do not use chemically sterilised syringes or needles.

Vaccination programme

A single two ml dose of reconstituted vaccine to be given 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.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

None.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Zero days.

4. IMMUNOLOGICAL INFORMATION

4.1 ATCvet code: QI02AB04.

The veterinary medicinal product induces specific antibodies against *Mannheimia haemolytica* biotype A, serotype 1 in vaccinated animals.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

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

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.
Shelf life after reconstitution according to directions: use immediately.

5.3 Special precautions for storage

Store in a refrigerator (2 °C – 8 °C).
Do not freeze.
Protect from light.

5.4 Nature and composition of immediate packaging

A Type I glass vial containing 5, 10, 25 or 50 doses of lyophilisate component accompanied by a Type I glass vial of emulsion containing 10 ml, 20 ml, 50 ml or 100 ml.

Cardboard box containing one lyophilisate vial of 5, 10, 25 or 50 doses and one solvent vial of 10, 20, 50 or 100 ml respectively.

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

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 national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Zoetis Belgium S.A.

7. MARKETING AUTHORISATION NUMBER

Vm 60021/3019

8. DATE OF FIRST AUTHORISATION

2 July 1999

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

August 2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

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

Gavin Hall
Approved: 12 December 2025