SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rispoval Pasteurella

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 2 ml dose (2 ml) contains:

Active Substances:
Lyophilised fraction:
Leukotoxoid of *Mannheimia haemolytica* serotype A1, strain NL 1009
200 – 2196 RU*
Capsular antigens of *Mannheimia haemolytica* serotype A1, strain NL 1009
345 – 10208 RU*

*ELISA relative units.

Liquid fraction:
Adjuvants:

Amphigen base*** (liquid paraffin + soya lecithin)	0.025 ml
Liquid paraffin	0.075 ml
Aluminium (Al^{3+})	2.58 mg

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

For the full list of excipients, see Section 6.1.

3. PHARMACEUTICAL FORM

Lyophilisate and emulsion for injection.

4. CLINICAL PARTICULARS

4.1 Target Species

Cattle from 3 months of age.

4.2 Indications for Use, Specifying the Target Species

For active immunisation of cattle to reduce lesions and respiratory disease caused by *Mannheimia haemolytica* biotype A, serotype 1.
Studies carried out show that a single dose is sufficient to confer protection from challenge by *Mannheimia haemolytica* within 7 days of vaccination. The vaccine will protect animals for at least 17 weeks.

4.3 Contraindications

Do not vaccinate unhealthy animals, pregnant animals or heifers at the time of breeding.

4.4 Special warnings for each 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.

4.5 Special precautions for use

i) Special precautions for use in animals

None.

ii) 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.
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 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 further medical advice.
To the doctor:
This veterinary medicinal product contains mineral oil. Even if small amounts have been injected, accidental injection with this 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.

4.6 Adverse reactions (frequency and seriousness)

A transient local swelling at the injection site is very commonly observed within 24 to 48 hours post vaccination. The swellings are up to 14 cm in diameter and usually disappear within 2 weeks post vaccination, with no need for treatment. On rare occasions, the local reaction may take longer to resolve (up to 52 days).

A transient increase in rectal temperature (up to a maximum of 40.9°C) is very commonly observed within 1 to 4 hours post vaccination. Temperatures return to normal within 4 days without treatment.

Rarely, hypersensitivity reactions may occur. In such cases, appropriate treatment e.g. adrenaline and/or antihistamine should be given without delay. Muscular trembling has also been noted very rarely."
The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports)

4.7 Use during pregnancy, lactation or lay

Do not vaccinate pregnant animals and heifers at the time of breeding.

4.8 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.

4.9 Amounts to be administered and administration route

Reconstitute the vaccine by first shaking the vial containing the emulsion, and then aseptically withdraw and add all of 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.
A single dose of vaccine will protect animals for at least 17 weeks. 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.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

Administration of an overdose is not expected to result in adverse effects other than those described in Section 4.6 for a single dose.

4.11 Withdrawal Period(s)

Zero days

5. IMMUNOLOGICAL PROPERTIES

ATCVet Code: QI02AB04
Rispoval Pasteurella induces specific antibodies against *Mannheimia haemolytica* biotype A, serotype 1 in vaccinated animals.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lyophilised fraction:
Phosphate Buffered Saline

Liquid fraction:
Liquid paraffin
Aluminium hydroxide
Soya lecithin
Polysorbate 80
Sorbitan oleate
Phosphate Buffered Saline

6.2 Incompatibilities

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

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 36 months.
Shelf-life after first opening the immediate container: Use immediately after reconstitution.

6.4 Special Precautions for Storage

Store away from light between +2°C and +8°C. Do not freeze.

6.5 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 10ml, 20ml, 50ml or 100ml. Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products, if appropriate

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

7. MARKETING AUTHORISATION HOLDER

Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

8. MARKETING AUTHORISATION NUMBER

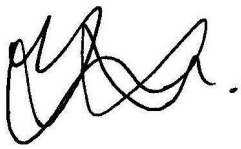
Vm 42058/4128

9. DATE OF THE FIRST AUTHORISATION

02 July 1999

10. DATE OF REVISION OF THE TEXT

May 2020



Approved: 01 May 2020