ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Rispoval Pasteurella – Outer Carton
1x 5 doses
1x 10 doses
1x 25 doses
1x 50 doses

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rispoval Pasteurella

2. STATEMENT OF ACTIVE SUBSTANCES

Inactivated *Mannheimia haemolytica* vaccine
Rispoval Pasteurella is composed of a lyophilisate containing inactivated Leukotoxoid (between 200 and 2196 RU*) and Capsular antigens (between 345 and 10208 RU*) of *Mannheimia haemolytica* biotype A, serotype 1. When reconstituted with emulsion component, the reconstituted vaccine contains aluminium hydroxide and liquid paraffin.
* Relative Units.

3. PHARMACEUTICAL FORM

Lyophilisate and emulsion for injection

4. PACKAGE SIZE

5 doses of 2 ml each
10 doses of 2 ml each
25 doses of 2 ml each
50 doses of 2 ml each

5. TARGET SPECIES

Cattle from 3 months of age.

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

ROUTE:
Intramuscular injection. 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.

VACCINATION PROGRAMME:
A single dose to be given to healthy cattle over 3 months of age. Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

WITHDRAWAL PERIOD: Zero days

9. SPECIAL WARNING(S), IF NECESSARY

Accidental injection is dangerous – see package leaflet before use.

10. EXPIRY DATE

Exp date:
Use immediately after reconstitution.

11. SPECIAL STORAGE CONDITIONS

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

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

DISPOSAL:
Read package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

FOR ANIMAL TREATMENT ONLY

POM-V
To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

KEEP OUT OF THE SIGHT AND REACH OF CHILDREN

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Zoetis Belgium S.A.
2nd Floor, Building 10
Cherrywood Business Park
Loughlinstown
Dublin 18
D18 T3Y1
Ireland

16. MARKETING AUTHORISATION NUMBER

Vm 60021/3019

17. MANUFACTURER'S BATCH NUMBER

Lot No:

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Rispoval Pasteurella – Lyophilisate Vial Label
5 dose
10 dose
25 dose
50 dose

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rispoval Pasteurella

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Inactivated *Mannheimiahaemolytica* vaccine
Lyophilisate containing inactivated Leukotoxoid (between 200 and 2196 RU*) and Capsular antigens (between 345 and 10208 RU*) of *Mannheimia haemolytica* biotype A, serotype 1, with aluminium hydroxide and liquid paraffin as adjuvant following reconstitution.
* Relative Units.

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

5 doses of 2 ml each
10 doses of 2 ml each
25 doses of 2 ml each
50 doses of 2 ml each

4. ROUTE(S) OF ADMINISTRATION

Administer IM to cattle

5. WITHDRAWAL PERIOD(S)

Withdrawal period: zero days.

6. BATCH NUMBER

Lot No:

7. EXPIRY DATE

Exp date:
Use immediately after reconstitution

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Rispoval Pasteurella – Emulsion Vial Label
5 dose
10 dose
25 dose
50 dose

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rispoval Pasteurella

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Inactivated *Mannheimia haemolytica* vaccine
Emulsion containing aluminium hydroxide and liquid paraffin as adjuvant.

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

5 doses of 2 ml each
10 doses of 2 ml each
25 doses of 2 ml each
50 doses of 2 ml each

4. ROUTE(S) OF ADMINISTRATION

Administer IM to cattle

5. WITHDRAWAL PERIOD(S)

Withdrawal period: zero days.

6. BATCH NUMBER

Lot No:

7. EXPIRY DATE

Exp date:

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
Rispoval Pasteurella

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:
Zoetis Belgium S.A.
2nd Floor, Building 10
Cherrywood Business Park
Loughlinstown
Dublin 18
D18 T3Y1
Ireland

Manufacturer responsible for batch release:
Zoetis Belgium SA
Rue Laid Burniat 1
1348 Louvain-la-Neuve
Belgium

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ripsoval Pasteurella
Lyophilisate and emulsion for injection.

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Inactivated, adjuvanted *Mannheimia haemolytica* vaccine. An off-white lyophilisate containing antigens of *Mannheimia haemolytica* biotype A, serotype 1, strain NL 1009:

Leukotoxoid	200 – 2196 RU*
Capsular antigens	345 – 10208 R.U*

*ELISA relative units.
Supplied together with a vial of emulsion containing aluminium hydroxide and liquid paraffin as adjuvant.

4. INDICATION(S)

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.

5. CONTRAINDICATIONS

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

6. ADVERSE REACTIONS

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)

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Cattle over 3 months of age.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) 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.
A single dose of 2 ml of reconstituted 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.

9. ADVICE ON CORRECT ADMINISTRATION

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.
Do not use chemically sterilised syringes or needles.

10. WITHDRAWAL PERIOD(S)

Zero days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Store away from light between +2°C and +8°C. Do not freeze. Reconstituted vaccine should be used immediately.
Do not use after the expiry date stated on the label.

12. SPECIAL WARNING(S)

To be supplied only on veterinary prescription.
For animal treatment only.

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.

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 th 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.

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

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.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

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

14. 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.

15. OTHER INFORMATION

Packs containing a 5, 10, 25 or 50 dose vial of lyophilisate are available, together with a vial of emulsion containing 10, 20, 50 or 100 ml. Not all pack sizes may be marketed.

Gavin Hall

Approved 15 November 2024