IRISH MEDICINES BOARD ACT 1995

EUROPEAN COMMUNITIES (ANIMAL REMEDIES) (No. 2) REGULATIONS 2007

(S.I. No. 786 of 2007)

VPA: **10019/069/001**
Case No: 7003582

The Irish Medicines Board in exercise of the powers conferred on it by Animal Remedies (No. 2) Regulations (S.I. No. 786 of 2007) hereby grants to:

Pfizer Healthcare Ireland

Trading as Pfizer Animal Health, **Ringaskiddy**, **Co. Cork**, **Ireland**

an authorisation, subject to the provisions of the said Regulations and the general conditions of the attached authorisation, in respect of the Veterinary Medicinal Product:

Rispoval Pasteurella

The particulars of which are set out in Part 1 and Part 2 of the said Schedule. The authorisation is also subject to any special conditions as may be specified in the said Schedule.

The authorisation,unless revoked, shall continue in force from **30/07/2008**.

Signed on behalf of the Irish Medicines Board

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A person authorised in that behalf by the said Board.

(NOTE: This authorisation replaces any previous authorisation in respect of this product which is now null and void.)

Part II

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Rispoval™ Pasteurella

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance(s):	per dose (2 ml)
Inactivated antigens of *Pasteurella haemolytica* biotype A, serotype 1, strain NL 1009.	
Leukotoxoid	380 – 1276 R.U*
Capsular antigens	565 - 10208 R.U*

* Results are expressed as ELISA relative units (R.U.) per dose.

Solvent:

Adjuvants:
Liquid paraffin and Aluminium hydroxide.

For a full list of excipents, 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 *Pasteurella haemolytica* biotype A, serotype 1.

Studies carried out show that a single dose is sufficient to confer protection from challenge by *Pasteurella 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 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

Special precautions for use in animals

None.

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 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 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)

Very rarely hypersensitivity reactions may occur. In such cases, appropriate treatment e.g. adrenaline and/or antihistamine should be given without delay.

A mild, transient fever might be observed 24 to 48 hours after vaccination in some animals. Temperatures return to normal in the following 24 to 48 hours, without remedial action.

A mild, transient local swelling might be observed at the site of injection 24 to 48 hours after vaccination in a small number of animals. These swellings do not generally cause discomfort to the animals even on palpation. The average size of reaction 48 hours after vaccination was 5 cm in diameter, reducing to half that size by day 5. In the majority of cases site reactions are undetectable by 14 days after vaccination but very occasionally might be observed for up to 48 days.

Short-term discomfort around the injection site and muscular trembling have been noted very rarely.

4.7 Use during pregnancy, lactation or lay

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

4.8 Interaction with other medicinal products and other forms of interaction

This vaccine can safely be administered, but not mixed with, Rispoval RS. Except for Rispoval RS, no information is available on the compatibility of this vaccine with any other. Therefore the safety and efficacy of this product when used with any other (either when used on the same day or at different times) has not been demonstrated.

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 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

ATC Vet Code: QI02AB04

Rispoval Pasteurella induces specific antibodies against *Pasteurella haemolytica* biotype A, serotype 1 in vaccinated animals.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Liquid paraffin
Aluminium hydroxide
Soya lecithin
Polysorbate 80
Sorbitan oleate
Phophate Buffered Saline

6.2 Incompatibilities

Do not mix with any other 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

Any unused product or waste material should be disposed of in accordance with national requirements.

7 MARKETING AUTHORISATION HOLDER

Pfizer Healthcare Ireland,

Trading as:

Pfizer Animal Health,

Ringaskiddy,

Co. Cork,

Ireland.

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10019/69/1

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

11th April 2006

10 DATE OF REVISION OF THE TEXT

June 2008