IRISH MEDICINES BOARD ACT 1995

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

(S.I. No. 786 of 2007)

VPA: **10857/030/001A**
Case No: 7004763

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:

Merial Animal Health Limited

Sandringham House, **Sandringham Avenue, Harlow Business Park, Harlow**, **Essex CM19 5TG**, **United Kingdom**

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:

Hyoresp

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 **10/06/2008**.

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

HYORESP

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Per one dose of 2 ml:
Active substance:
. Inactivated whole cell *Mycoplasma hyopneumoniae* antigen, at least ..... 3.0 ELISA.U*

Adjuvant:
. Al^{+++} (as hydroxide) ..... 4.2 mg

Excipients:
. Thiomersal ..... 0.2 mg

* ELISA.U: Unit of RP (relative potency) compared to reference vaccine.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Suspension for injection. Milky colour

4 CLINICAL PARTICULARS

4.1 Target Species

- Suckling piglets from the age of 5 days
- Post weaning piglets
- Fattening pigs

4.2 Indications for use, specifying the target species

For active immunisation of pigs to reduce infection and lung lesions caused by *Mycoplasma hyopneumoniae.*

4.3 Contraindications

None. See 4.7

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

Apply usual procedures for the handling of the animals.
Vaccinate only healthy animals.
Shake prior to use.
Apply usual aseptic procedures.

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

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

4.6 Adverse reactions (frequency and seriousness)

Administration of the vaccine may cause transient oedema and muscular inflammation at the site of injection, not usually exceeding one week and rarely up to five weeks.
The vaccination may cause a slight temperature increase (less than 1°C) for a transient period (less than 24 hours after administration) without any effect on the animals health or zootechnical performance.
In exceptional cases, the vaccine may reveal a hypersensitivity status. Appropriate symptomatic treatment should be administered.

4.7 Use during pregnancy, lactation or lay

In the absence of data, the use of this vaccine is not recommended in breeding animals.

4.8 Interaction with other medicinal products and other forms of interaction

No information is available on the compatability of this vaccine with any other. Therefore the safety and efficacy of this product when used with any other vaccine has not been demonstrated.

4.9 Amounts to be administered and administration route

Inject one 2-ml dose of vaccine by intramuscular route, according to one of the following schedules:
- 2 injections at an interval of 3-4 weeks from 5 days of age.
- or 1 injection from ten weeks of age.

The choice of the vaccination regimen should be based on the knowledge of the risks (time of occurrence of infection) in the herd. Vaccination must be performed prior to animals becoming infected. The single injection regimen will be limited to cases where animal infection occurs during the mid to late fattening period.

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

No side effect has been observed after the administration of an overdose except those mentioned in the “Adverse Reactions” section.

4.11 Withdrawal Period(s)

Zero days.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

ATC vet code: QI09AB13 (Mycoplasma vaccine)

HYORESP is an inactivated and adjuvanted vaccine which stimulates active immunity against *Mycoplasma hyopneumoniae*.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Aluminium hydroxide
Thiomersal
Saline Solution

6.2 Incompatibilities

Do not mix with any other vaccine or immunological product.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 2 years
Shelf-life after first opening the immediate packaging: 24 hours.

6.4 Special precautions for storage

Store and transport refrigerated (2°C – 8°C), protected from light.

6.5 Nature and composition of immediate packaging

Packaging intended for sale:
Cardboard box with one Type I glass bottle of 10, 20, 50, or 100 ml with a butyl elastomer closure and aluminium cap.
Cardboard box with ten Type I glass bottles of 10, 20, 50, or 100 ml with a butyl elastomer closure and aluminium cap.
Cardboard box with one Type I polypropylene bottle of 100 or 200 ml with a butyl elastomer closure and aluminium cap.
Cardboard box with ten Type I polypropylene bottles of 100 or 200 ml with a butyl elastomer closure and aluminium cap.

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

Merial Animal Health Limited
Sandringham House, Sandringham Avenue
Harlow Business Park, Harlow
Essex CM19 5TG
United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10857/30/1

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

25th November 2007

10 DATE OF REVISION OF THE TEXT

10th June 2008