IRISH MEDICINES BOARD ACT 1995

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

(S.I. No. 786 of 2007)

VPA: **10996/099/001**
Case No: 7004495

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:

Intervet Ireland Limited

Magna Drive, **Magna Business Park**, **Dublin 24**, **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:

Porcilis Porcol 5

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 **27/10/2007**.

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

Porcilis Porcol 5

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substances:	per dose of 2 ml:
Inactivated *E. coli* antigens:	
LT toxoid	at least100 ED_{50}*
F4ab (K88ab) antigen	at least100 ED_{50}
F4ac (K88ac) antigen	at least100 ED_{50}
F5 (K99) antigen	at least100 ED_{50}
F6 (987 P) antigen	at least100 ED_{50}

Adjuvant:
Liquid paraffin

Excipients:
Preservative
Formaldehyde

* Effective dose 50% in potency (seroconversion) test

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Emulsion for injection

4 CLINICAL PARTICULARS

4.1 Target Species

Pigs (sows and gilts)

4.2 Indications for use, specifying the target species

For the passive immunisation of piglets by active immunisation of sows/gilts to reduce mortality and clinical signs such as diarrhoea due to neonatal enterotoxicosis during the first days of life, caused by those *E.coli* strain which express the fimbrial adhesins F4ab (K88ab), F4ac (K88ac), F5 (K99) or F6 (987 P) and/or produce LT.

4.3 Contraindications

None

4.4 Special warnings for each target species

Do not vaccinate sick animals.
Not all cases of diarrhoea in piglets are due to *E.coli.*
A good immune response is reliant on the reaction of an immunogenic agent and a fully competent immune system.
Immunogenicity of the vaccine antigen will be reduced by poor storage or inappropriate administration.
Immunocompetence of the animal may be compromised by a variety of factors including poor health, nutritional status, genetic factors, concurrent drug therapy and stress.

4.5 Special precautions for use

Special precautions for use in animals

Vaccination of sows during the last 2 weeks of gestation could be of risk to the sow and her litter and is best avoided.

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

To the user:
This product contains mineral oil. Accidental/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 insert with you.
If pain persists for more than 12 hours after medical examination, seek medical advice again.

To the physician:
This product contains mineral oil. Even if small amounts have been injected, accidental injection with this oil-based product can cause intense vascular spasm which may, for example, result in ischaemic necrosis and 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)

Slight hyperthermia (increase of up to about 1°C) may occur in the first 24 hours after vaccination. A temporary swelling (from 1 to 6 cm across) at the site of injection may be present for up to 5 days, and local tissue reactions in the form of abscesses may occur in most animals. Six weeks after vaccination these local reactions are considerably decreased. In a proportion of animals small granulomatous lesions may be identified in the region of the injection site at slaughter.

4.7 Use during pregnancy, lactation or lay

Can be used during pregnancy.

4.8 Interaction with other medicinal products and other forms of interaction

No information is available on the safety and efficacy from the concurrent use of this vaccine with any other. It is therefore recommended that no other vaccines should be administered within 14 days before or after vaccination with this product.

4.9 Amounts to be administered and administration route

Intramuscular injection in sows/gilts of 2 ml of the vaccine per animal in the neck area behind the ear.
The use of a 16g x 1.5 inch hypodermic needle is recommended.
Basic vaccination scheme: Two injections 5-6 weeks apart.
Re-vaccination scheme: Single injection at intervals of 6 months.

Allow vaccine to reach ambient temperature (15-25^{o}C) before use.
Shake vigorously before and at intervals during use.
Clean and sterile vaccination equipment should be used and care should be taken to administer the vaccine in an aseptic fashion.

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

The same effects are seen as with a single dose (see 4.6 above).

4.11 Withdrawal Period(s)

Zero days

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: inactivated bacterial vaccine ATC vet code: QI09AB02

Vaccine to stimulate active immunity of sows/gilt in order to provide passive immunity to their progeny against *E.coli* strains that express the fimbrial antigens F4ab (K88ab), F4ac (K88ac), F5 (K99) and F6 (987 P) and/or produce LT.

The fimbrial adhesins F4ab, F4ac, F5 and F6 are responsible for the adhesion and the virulence of *E.coli* strains which cause neonatal enterotoxicosis in piglets. These immunogens are incorporated in an adjuvant in order to give a prolonged stimulation of immunity. Neonatal piglets derive passive immunity via ingestion of colostrum from vaccinated sows/gilts.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Liquid paraffin
Formaldehyde
Polysorbate 80
Sorbitan monooleate
Sodium chloride
Water for injection

6.2 Incompatibilities

Do not mix with any other vaccine/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: 3 hours

6.4 Special precautions for storage

Store between +2 and +8^{o}C. Store out of light. Do not freeze.

6.5 Nature and composition of immediate packaging

Carton containing 1 glass Type II or Polyethylene Terephthalate (PET) bottle of 20ml or 50ml closed with a nitryl rubber stopper and colour coded aluminium cap.

Not all pack sizes are 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

Intervet Ireland Ltd.
Magna Drive
Magna Business Park
Citywest Road
Dublin 24

8 MARKETING AUTHORISATION NUMBER(S)

VPA No. 10996/99/1

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

24th October 2007

10 DATE OF REVISION OF THE TEXT

22nd May 2008