IRISH MEDICINES BOARD ACT 1995

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

(S.I. No. 786 of 2007)

10019/176/001
Case No: 7007815

Transferred from 10861/093/001.

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

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:

Poulvac iSE

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 **14/05/2010** until **30/05/2011**.

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

POULVAC iSE

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active ingredients:	**Per dose (0.5 ml)**
Salmonella Enteritidis, phage type 4, inactivated	3-6x10^8 CFU*
Adjuvant:	**Per dose (0.5 ml)**
White oil	0.3325 ml
Sorbitan sesquioleate	0.0175 ml
Polysorbate 80	0.0028 ml
Excipients:	**Per dose (0.5 ml)**
Saline solution	to 0.5 ml

* Potency : statistical reduction of *Salmonella* Enteritidis positive birds in vaccination/challenge test.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Emulsion for injection.
Homogeneous white-ivory emulsion.

4 CLINICAL PARTICULARS

4.1 Target Species

Chickens (future breeder and future layer pullets).

4.2 Indications for use, specifying the target species

Active immunisation of 12 to 13 weeks old chickens – future layers and future breeders - to reduce the infection of internal organs (spleen, liver, and caeca) by *Salmonella* Enteritidis and to reduce the shedding of *Salmonella* Enteritidis.
Reduction in egg shell contamination was not investigated.

Onset of immunity: 3 weeks after the primary vaccination.
Duration of immunity: 9 months.

4.3 Contraindications

Do not use in birds in lay.
See section 4.7.

4.4 Special warnings for each target species

The safety of the vaccine has not been assessed in breeder birds; in particular, no information is available concerning potential adverse effects on fertility and hatchability.

4.5 Special precautions for use

Special precautions for use in animals
Vaccination will not interfere with *Salmonella* Enteritidis monitoring programs based on bacteriological reisolation, but will interfere with programs based on seroagglutination or antibody detection assays.
Vaccination may cause cross-reactions in serological tests for *Salmonella* Gallinarum / Pullorum (plate agglutination assays).

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

No palpable swellings are reported after the first vaccination. Palpable swellings may temporarily develop in about half of the vaccinated birds following the second vaccination. Most swellings with average size of
1.7 cm x 5.1 cm disappear within 14 days. In some cases, swellings may persist for more than 3 weeks. Swellings may include granuloma and fibrosis, and, incidentally, abscesses.

A transient delay in the onset of lay and an increase in downgraded eggs can occur, with no impact on peak production or overall laying rate of normal eggs.

4.7 Use during pregnancy, lactation or lay

Do not use in birds in lay.
Do not vaccinate birds within 2 weeks before onset of lay.

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 the product.

4.9 Amounts to be administered and administration route

Method of administration :
Intramuscular, in the breast muscle.
It is recommended to use a closed multi-injection vaccination system.

Vaccination schedule :
Twice a single 0.5 ml dose per bird with an interval of 4 weeks, the first dose being administered at the age of 12 to 13 weeks.

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

Administration of a double dose was shown not to cause effects other than those recorded following administration of one dose, as described in section 4.6.

4.11 Withdrawal Period(s)

Zero days

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

ATCVet Code: QI01AB01

Salmonella Enteritidis vaccine (inactivated) for chickens.

To stimulate active immunity against *Salmonella* Enteritidis.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium chloride
Water for injections

6.2 Incompatibilities

Do not mix with any other vaccine/immunological product.

6.3 Shelf-life

24 months
Broached bottles: Use immediately after broaching.

6.4 Special precautions for storage

Store and transport refrigerated (2 °C - 8 °C).
Protect from light.
Do not freeze.

6.5 Nature and composition of immediate packaging

Nature of the primary container
500 ml high density polyethylene (Ph. Eur.) bottle containing 1000 doses.
Chlorobutyl isoprene rubber stopper (Ph. Eur.) with aluminium cap.

Packaging
Carton box of 1 bottle of 1000 doses
Carton box of 10 bottles of 1000 doses

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 the national requirements

7 MARKETING AUTHORISATION HOLDER

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

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10019/176/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

31st May 2006

10 DATE OF REVISION OF THE TEXT

14th May 2010

Prohibition of sale and supply and/or use:

The Diseases of Animals Act, 1966 (Control on Animal and Poultry Vaccines) Order 2002 (S.I. No. 528 of 2002) applies in the case of the disease referred to in Part III Paragraph 5.2, of the schedule to this authorisation. The Veterinary Product Authorisation is therefore subject to specific licensing requirements under the aforementioned legislation. The Immunological Animal Remedy shall not be imported, sold or administered except in accordance with a licence granted under the Statutory Instrument No 528 of 2002.