

IRISH MEDICINES BOARD ACT 1995

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

(S.I. No. 786 of 2007)

VPA: **10996/175/001**

Case No: 7000438

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:

Norvax Compact 4

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 **03/11/2008**.

Signed on behalf of the Irish Medicines Board

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

Norvax Compact 4

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance(s)	per dose(0.1 ml)
<i>Aeromonas salmonicida</i> subsp. <i>Salmonicida</i> , strain FT 449	7.2 x 10 ⁷ bacteria, RPS ₆₀ ≥ 80 ¹
<i>Vibrio salmonicida</i> , strain NCMB 2262	7.2 x 10 ⁷ bacteria, RPS ₆₀ ≥ 90
<i>Vibrio anguillarum</i> serovar O1, strain Ft 257	3.6 x 10 ⁷ bacteria, RPS ₆₀ ≥ 75
<i>Vibrio anguillarum</i> serovar O2a, strain Ft 256	3.6 x 10 ⁷ bacteria, RPS ₆₀ ≥ 75
Adjuvant:	
Montanide ISA 763A oil	63.5mg

For a full list of excipients, see section 6.1

[1] Measured in the batch release potency test. $RPS_{60} = \text{Relative percent survival at 60\% control mortality} = (1 - \{\% \text{vaccinate mortality} / 60\% \text{ control mortality}\}) \times 100$

3 PHARMACEUTICAL FORM

Emulsion for injection. White to nearly white.

4 CLINICAL PARTICULARS

4.1 Target Species

Fish (Atlantic salmon (*Salmo salar*)).

4.2 Indications for use, specifying the target species

For active immunisation of Atlantic salmon (of minimum 35 g) to reduce mortality due to the diseases furunculosis caused by *Aeromonas salmonicida* subsp. *salmonicida*, coldwater vibriosis caused by *Vibrio salmonicida*, vibriosis caused by *Vibrio anguillarum* serovar O1 and/or *Vibrio anguillarum* serovar O2a.

Onset of immunity: 500 degree days.

Immunity against diseases has been demonstrated for up to 33 weeks post vaccination by challenge studies and 47 weeks post vaccination by antibody studies.

4.3 Contraindications

None.

4.4 Special warnings for each target species

Only healthy fish should be vaccinated.

4.5 Special precautions for use

Special precautions for use in animals

Fish should not be transferred to water in which exposure to furunculosis, coldwater vibriosis or vibriosis may occur until at least 500 degree days post-vaccination.

Vaccination at or below a temperature of 15°C is recommended.

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.

Personal protective equipment consisting of e.g. needle guard should be used when handling the product.

4.6 Adverse reactions (frequency and seriousness)

When undesirable effects occur, they are normally seen in the abdominal cavity.

Vaccinated animals normally show very slight to moderate adhesions between viscera or between viscera and the abdominal wall. The eventual adhesions may be removed manually and are thus not severe. (These descriptions equal Spielberg scores of 1-3).

Occasionally vaccinated populations may show adhesions between greater parts of the abdominal organs, granulomas and/or more massive pigmentation. Such lesions are typically seen in less than 10% of the treated animals. (This description equals Spielberg scores of 4 or more).

4.7 Use during pregnancy, lactation or lay

Do not use in breeding stock.

4.8 Interaction with other medicinal products and other forms of interaction

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. It is therefore recommended that no other vaccines should be administered within 168 degree days before or after vaccination with the product.

4.9 Amounts to be administered and administration route

Vaccination is recommended for fish of minimum 35 grams.

To lower the risk of accidental injection into internal organs the fish should be starved for a suitable period prior to vaccination in order to minimise the distension of the intestinal tract. The fish should be anaesthetised and vaccinated according to veterinary instructions. Inject 0.1 ml intraperitoneally along the central line, approximately one fin lengths in front of the pelvic fin base. The injection volume (dose) is independent of the fish size.

The size (length and diameter) of the needle should be suitable for the vaccine and the size of the fish. Select the length of the needle in order to assure it penetrates 1 to 2 millimeter into the abdominal cavity. Avoid injection into the internal organs. Ensure that the recommended dose is deposited into the abdominal cavity before the needle is withdrawn.

Sterile injection equipment should be used. Shake well before use. Standard vaccination equipment including “cradle with neck cord” can be supplied on request.

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

Administration of an overdose may result in increased local reactions compared to single dose administration.
Emergency procedures and antidotes: not applicable.

4.11 Withdrawal Period(s)

Zero degree days.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Stimulates active immunity against *Aeromonas salmonicida* subsp. *salmonicida*, *Vibrio salmonicida*, *Vibrio anguillarum* serovar O1 and *Vibrio anguillarum* serovar O2a in Atlantic salmon.

ATC vet code: QI10AB02 (Atlantic salmon).

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Montanide ISA 763A oil
Phosphate buffered saline

6.2 Incompatibilities

Do not mix with any other medicinal product.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 3 years

Shelf-life after first opening the immediate packaging: 4 hours

6.4 Special precautions for storage

Store and transport refrigerated (2°C – 8°C). Do not freeze.

6.5 Nature and composition of immediate packaging

Polyethylene terephthalate (PET) bottles with 250 ml (2500 doses), 500 ml (5000 doses) or 1000 ml (10,000 doses).
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

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

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10996/175/1

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

29th July 2003 / 29th July 2008