IRISH MEDICINES BOARD ACT 1995

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

(S.I. No. 786 of 2007)

VPA: **10974/019/001**
Case No: 7003900

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:

Novartis Animal Vaccines Ltd

4 Warner Drive, **Springwood Industrial Estate, Rayne Road**, **Essex CM7 2YW**, **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:

Furogen 2 Injection Vaccine

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 previously revoked, shall continue in force from **19/12/2007**.

Signed on behalf of the Irish Medicines Board

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A person authorised in that behalf by the said Board.

(NOTE: From this date of effect, 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

Furogen 2 Injection Vaccine

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance

Aeromonas salmonicida (As27)	Min. 2.6 x 10^8 cfu*/ml Max. 1.8 x 10^9 cfu/ml *cfu = colony forming units

Adjuvant

Mineral Oil

Excipient

Formaldeyde

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Emulsion for injection.

4 CLINICAL PARTICULARS

4.1 Target Species

Atlantic salmon (Salmo salar) ≥ 35g.

4.2 Indications for use, specifying the target species

To reduce furunculosis related mortality of Atlantic salmon populations by active immunisation against *Aeromonas salmonicida*. Onset of immunity occurs within 400 degree days following vaccination. Laboratory studies have indicated immunity to challenge is greatest at 1,200 degree days post vaccination. Duration of protection has been demonstrated for up to 6 months.

4.3 Contraindications

Do not use in fish selected for broodstock.

4.4 Special warnings for each target species

Vaccinate only healthy fish. Do not use if there are any signs of furunculosis in the fish. It is recommended that all fish within the stock population are vaccinated in order to reduce infection spread. It is recommended that vaccination should precede exposure to the disease agent by 400 degree days (number of days multiplied by the mean water temperature over the period in degrees Celsius).

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

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 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)

This vaccine will cause some degree of visceral adhesions within the peritoneal cavity, characteristic of vaccines that incorporate an oil adjuvant. Adhesions may be severe if vaccine is not properly injected and deposited into the body cavity. Mild adhesions (Speilberg Score 1-2) are those that occur around the injection site and may adhere to adjacent internal tissues. Moderate lesions (Speilberg Score 3-4) are more pronounced and may cause organs to adhere to the abdominal wall. Severe adhesions (Speilberg Score 4-6) affect all organs in the peritoneal cavity, including the oesophagus, and internal organs are fused into a single mass.

Localised pigmentation may occur.

4.7 Use during pregnancy, lactation or lay

Not applicable

Fertility

Do not use in fish selected for broodstock.

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.

4.9 Amounts to be administered and administration route

For intraperitoneal injection. Each litre of vaccine is sufficient to vaccinate 10,000 fish. To use, fish are anaesthetised until immobilised and administered 0.1ml of the vaccine intraperitoneally on the midline, one pelvic fin length ahead of the pelvic fin girdle. It is recommended that fish be 35 g or more in size for injection administration. The vaccine should be allowed to warm to 15-20°C prior to administration. A minimum water temperature of 2ºC for vaccination is recommended. Slight separation of oil from the vaccine may occur in storage. If so, DO NOT INJECT THE SEPARATED OIL COMPONENT but mix thoroughly before use.

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

Laboratory studies have indicated that weight gain will be depressed following double dose or repeat administration.

4.11 Withdrawal Period(s)

Zero degree days.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

For the active immunisation of Atlantic salmon against *Aeromonas salmonicida*.

ATCVet Code: QI10A B01

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Formaldehyde
Polysorbate 80
Sorbitan sesquioleate
Trypticase Soy broth
Simeticone
Sodium Hydroxide
Hydrogen Chloride

6.2 Incompatibilities

Do not mix with any other medicinal product.

6.3 Shelf-life

Shelf-life as packaged for sale: 18 months.
Shelf-life after first opening: Use within 6 hours.

6.4 Special precautions for storage

Store in a refrigerator (2 °C- 8°C). Protect from light. Do not freeze.

6.5 Nature and composition of immediate packaging

1000 ml EVA (plastic) intravenous bag with a plastic screw cap (ABS terluran/high density polyethylene) closure and a plastic clamp-off device.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

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

7 MARKETING AUTHORISATION HOLDER

Novartis Animal Vaccines Limited
4, Warner Drive,
Springwood Industrial Estate
Rayne Road, BRAINTREE,
Essex CM7 2YW

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10974/019/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

19th December 2007

10 DATE OF REVISION OF THE TEXT