Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

AquaVac FNM^{PLUS}
Emulsion for injection for fish.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance	**per dose**
Inactivated cells of *Aeromonas salmonicida*	
strain MT004	RPS_{60}[1] ≥ 80% after vaccination
strain MT423	

[1]RPS_{60} = relative percentage survival in vaccinates at 60% control mortality

Adjuvant

Montanide ISA 711	0.07 ml

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.

4.2 Indications for use, specifying the target species

For the reduction of mortality due to furunculosis disease caused by *Aeromonas salmonicida* in Atlantic salmon of at least 25 g.
Immunity develops progressively after vaccination, the rate being dependent upon water temperature.
At 12°C, a minimum of 28 days should be allowed between vaccination and anticipated exposure to infection. For general guidance, a period equivalent to 400 degree-days should be allowed for development of optimum immunity. Duration of immunity has been demonstrated under field conditions for at least 5 months after vaccination.

4.3 Contraindications

Do not vaccinate fish with AquaVac FNM^{PLUS} more than once.

4.4 Special warnings for each target species

Do not vaccinate fish at water temperatures below 1ºC.

4.5 Special precautions for use

Special precautions for use in animals

Do not vaccinate fish during the smoltification process.
Vaccinate only healthy fish.
The vaccine should be administered using a multi-dose injection applicator incorporating a mechanism to prevent flush-back. This applies equally to hand-held and automatic systems. Careful injection technique is important to minimise adverse reactions.

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

Warning to the user: This product contains oil (Montanide). Accidental injection/self injection may result in severe pain and swelling, particularly if injected into a joint of 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.
Information for the physician: this product contains oil (Montanide). Even if small amounts have been injected, accidental injection with this product can cause intense swelling, which may, for example, result in ischemic 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)

Some inflammation in the body cavity is normal in the vicinity of the injection site and is part of the immune response. Side effects in the form of visceral adhesions occur in the majority of fish, but are minor in extent (Speilberg score not more than 3). Some melanisation may occur in up to 1/3 fish.
External signs such as scale loss and haemorrhage at the point of injection and more serious internal reactions are rarely present if injection technique is good.
Slightly increased levels of fin rot are sometimes observed following vaccination against furunculosis.

4.7 Use during pregnancy, lactation or lay

Do not use in fish intended as brood stock.

4.8 Interaction with other medicinal products and other forms of interaction

No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product. A decision to use this vaccine before or after any other veterinary medicinal product therefore needs to be made on a case by case basis.

4.9 Amounts to be administered and administration route

The product is administered by intraperitoneal injection. Fish, previously anaesthetised with an approved anaesthetic, are injected centrally in the abdomen, 1 – 2 fin lengths in front of the base of the pelvic fins. The needle should point forward at an angle of about 45° and in a 25g fish, penetrate to a depth of approximately 2 - 3 mm.
The vaccine should be administered at a dose of 0.1 ml per fish.
The minimum size of fish for vaccination is 25g.
Semi-automatic injectors with valves preventing flushback should be used, with a 6 mm, 22 gauge needle.

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

No adverse observations have been noted as a result of administration of a double dose other than those mentioned in section 4.6.

4.11 Withdrawal Period(s)

Zero degree days.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

For the active immunisation of Atlantic salmon against furunculosis disease caused by *Aeromonas salmonicida.*
Pharmacotherapeutic group: Inactivated bacterial vaccine, Aeromonas.
ACT vet code: QI10AB01

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Formaldehyde
Sodium chloride solution

6.2 Incompatibilities

Do not mix with any other veterinary medicinal 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: 5 hours

6.4 Special precautions for storage

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

6.5 Nature and composition of immediate packaging

The product is supplied in 500ml (5000 dose) high-density polyethylene bottles with nitrile rubber stoppers and aluminium caps.

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

Any unused veterinary medicinal product or waste materials derived from the use of such veterinary medicinal product should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Intervet Ireland Ltd.

Magna Drive

Magna Business Park

Citywest Road

Dublin 24

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10996/219/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

23rd November 2010

10 DATE OF REVISION OF THE TEXT

February 2011