Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

AquaVac Furovac.
Concentrate for dip suspension or suspension for injection for Atlantic Salmon.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Per dose:

Active substance:
Inactivated cells of *Aeromonas salmonicida (*Strain MT004): $\geq 1 \times 10^9$ per cells/ml inducing RPS_{70}* ≥ 60%

* Relative percent survival in vaccinates at 70% control mortality

Excipients
Residual formaldehyde ≤ 0.5 mg/ml

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Concentrate for dip suspension or suspension for injection.

4 CLINICAL PARTICULARS

4.1 Target Species

Atlantic salmon (*Salmo salar*).

4.2 Indications for use, specifying the target species

For active immunisation of Atlantic salmon of at least 2g to reduce mortality from furunculosis caused by *Aeromonas salmonicida*.
The time for development of protective immunity will depend on the water temperature. 336 degree-days should be allowed between vaccination and anticipated exposure to infection (e.g. 28 days at a water temperature of 12ºC). Under laboratory conditions, after immersion vaccination of very small (2g) fish, a duration of immunity of up to 1080 degree days (90 days at 12°C) has been demonstrated, although the level of protection waned during this period (relative percentage survival 77% at 28 days, 42% at 90 days). No laboratory studies have been carried out to investigate duration of immunity after injection vaccination. Under field conditions, after injection vaccination of larger fish (35g) there is some evidence of duration of immunity of up to 4 months, and up to 6-9 months where immunity to vaccination is likely to have been boosted by natural challenge.

4.3 Contraindications

Do not vaccinate fish suspected of having furunculosis disease.
Do not vaccinate fish with Aquavac Furovac by injection more than once.

4.4 Special warnings for each target species

Do not vaccinate fish at water temperatures below 6°C.

4.5 Special precautions for use

Special precautions for use in animals
Only vaccinate healthy fish.
Do not vaccinate fish during smoltification

Special precautions to be taken by the person administering the veterinary medicinal product to animals
Protective equipment should be used to avoid self injection.
In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

4.6 Adverse reactions (frequency and seriousness)

Slight growth retardation was observed after immersion vaccination of very small (2g) fish.

4.7 Use during pregnancy, lactation or lay

In the absence of specific data, the vaccine should not be administered to broodstock or fish intended as broodstock.

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

Shake the bottle well before using.

Immersion vaccination - fish from 2g weight
The product is administered by immersion of the fish for 60 seconds in vaccine diluted 1 in 10 with hatchery water. (9 parts water to 1 part vaccine)
This process can be repeated, oxygenating the solution between each use with comparable weights of fish, using the same tank of diluted vaccine until 100 kg of fish have been treated per litre of undiluted vaccine. Thus for fish 20 g in weight, 5000 fish may be vaccinated per litre of vaccine. The temperature of diluted vaccine should not differ from the temperature of the water in the holding tank by more than ± 5° C.
The precise bacterial dose taken up by individual fish cannot be calculated.

Injection vaccination – fish from 20g weight
The vaccine must be administered using a multi-dose injection applicator incorporating a mechanism to prevent flush-back. This applies equally to hand-held and automatic systems.
The product is administered by intra-peritoneal injection in the ventral area, just anterior to the pelvic fins. The dose is 0.1 ml per fish.
The fish should be anaesthetised prior to vaccination, using an anaesthetic licensed for use on fish.

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

No adverse effects seen after 2x overdose injection vaccination.
Mortality of up to 6% has been seen after immersion vaccination with a 2x overdose, and growth retardation in very small (2g) fish.

4.11 Withdrawal Period(s)

Zero degree days.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

For the active immunisation of Atlantic salmon against furunculosis, caused by *Aeromonas salmonicida.*

Pharmacotherapeutic group: Inactivated bacterial vaccine, Aeromonas.
ATCvet 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

The vaccine has a shelf life of 24 months.
Vaccine should be used by injection within 5 hours of broaching the stopper. Any unused vaccine should be disposed o after this period.
When administering by immersion, dilute the contents immediately after opening the container, and use diluted vaccine immediately.

6.4 Special precautions for storage

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

6.5 Nature and composition of immediate packaging

The product is supplied in 1000 ml crimp-sealed high-density polyethylene bottles according to Ph. Eur.
Vaccination by injection = 10,000 doses
Vaccination by immersion = 100 Kg of fish.

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 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 10996/220/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

25th October 2010

10 DATE OF REVISION OF THE TEXT

February 2011