1. NAME OF THE VETERINARY MEDICINAL PRODUCT

AquaVac S7 emulsion for injection for Atlantic salmon

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 0.05 ml dose contains:

Active substances:

Infectious pancreatic necrosis virus (IPNV) serotype Sp, strain SP.2005.009, inactivated	≥ 0.75 ELISA units[1]
Aeromonas salmonicida subsp. *salmonicida*, strain FT 449, inactivated	≥ 9.7 $\log_2$ ELISA units[2]
Aliivibrio salmonicida, strain NCMB 2262, inactivated	≥ 90% RPS[3]
Vibrio anguillarum serotype O1, strain FT 257, inactivated	≥ 75% RPS[3]
Vibrio anguillarum serotype O2a, strain FT 256, inactivated	≥ 75% RPS[3]
Moritella viscosa, genotype CC1, strain RO 1.0, inactivated	≥ 5.8 $\log_2$ ELISA units[2]
Yersinia ruckeri, serotype O1, biotype 1, strain Hagerman, inactivated	≥ 85% RPS[3]

[1]Antigenic mass measured in the final product
[2]Serological response in Atlantic salmon
[3]RPS: relative percentage survival in a laboratory test in Atlantic salmon

Adjuvants:

Paraffin, light liquid	21.5 mg.

Excipients:

Qualitative composition of excipients and other constituents
Polysorbate 80
Sorbitan monooleate
Sodium chloride
Potassium chloride
Disodium phosphate dihydrate
Potassium dihydrogen phosphate
Water for injections

White to nearly white emulsion.

3. CLINICAL INFORMATION

3.1 Target species

Atlantic salmon.

3.2 Indications for use for each target species

For active immunisation of Atlantic salmon to reduce mortality caused by infections with IPNV (Infectious pancreatic necrosis), *Aeromonas salmonicida* subsp. *salmonicida* (furunculosis), *Aliivibrio salmonicida* (cold-water vibriosis), *Vibrio anguillarum* serotype O1 and O2a (vibriosis), *Moritella viscosa* genotype CC1 (winter ulcer disease), and *Yersinia ruckeri* serotype O1, biotype 1 strains (yersiniosis).

Onset of immunity: 469 degree days (dd) for *M. viscosa*, 500 dd for all other bacterial components, and 517 dd for IPNV.

Duration of immunity: 7 months for IPNV, and 12 months for the bacterial components

3.3 Contraindications

None.

3.4 Special warnings

Vaccinate healthy animals only.

3.5 Special precautions for use

Special precautions for safe use in the target species:
Vaccination is recommended for fish above 30 grams.
Feed should be withheld at least 2 days prior to vaccination. The fish should be anaesthetised before vaccination. The length and the diameter of the applied needle should be adapted to the actual fish size.
The vaccine should not be used in diseased or unhealthy fish, fish receiving medical treatment or fish during smoltification.
Do not vaccinate below 2.5°C or above 17°C.
Vaccination at high water temperatures (≥ 17°C) may increase local reactions.
Incorrect vaccination, stress and poor hygiene may lead to increased adverse events.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Personal protective equipment consisting of guarded needles or needle protectors should be used when administering the product.

In case of accidental self-injection, seek medical advice immediately and show the package leaflet or label to the physician.

To the user:
This veterinary medicinal 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 veterinary medicinal 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 veterinary medicinal product contains mineral oil. Even if small amounts have been injected, accidental injection with this veterinary medicinal 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.

Special precautions for the protection of the environment:
Not applicable.

3.6 Adverse events

Atlantic salmon:

Very common (>1 animal / 10 animals treated):	Adhesion in fish[1], Melanin accumulation in fish, Visible vaccine in fish, Reduced growth rate[2]
Common (1 to 10 animals / 100 animals treated):	Adhesion in fish[3].

[1]Speilberg score of 1 and 2.
[2]Observed in the immediate post vaccination period.
[3]Speilberg score of 3.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Fertility:
Do not use in broodstock. The possible effects of vaccination on spawning have not been investigated.

3.8 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.

3.9 Administration routes and dosage

Intraperitoneal use.
Shake the bottle well before use. Avoid formation of air bubbles.

Dosage: a single dose of 0.05 ml.
Administration: intraperitoneally along the central line, approximately 1 pelvic fin length in front of the pelvic fin base.

Vaccination equipment must be thoroughly cleaned/sterilized before use and used by trained personnel.
It is important to ensure that air is removed from the vaccination equipment before vaccination and that the entire vaccine dose is deposited into the abdominal cavity before the needle is withdrawn.
Vaccination equipment must be calibrated according to the manufacturer's recommendations before use. Regular dose monitoring is recommended.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

Following the administration of an overdose (0.1 ml), no adverse events other than those described in section 3.6 were observed, however Speilberg scores for adhesions in fish were higher; Speilberg scores ranging from 1 to 3 were very common, and a Speilberg score of 4 was uncommon.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Zero degree days.

4. IMMUNOLOGICAL INFORMATION

4.1 ATCvet code: QI10AL06.

Stimulates active immunity against infectious pancreatic necrosis, furunculosis, cold-water vibriosis, vibriosis, winter ulcer disease, and yersiniosis in Atlantic salmon.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 18 months.
Shelf life after first opening the immediate packaging: use within 2 days.

5.3 Special precautions for storage

Store in a refrigerator (2 °C – 8 °C).
Do not freeze.
Protect from direct sunlight.

5.4 Nature and composition of immediate packaging

Bottles of polyethylene terephthalate (PET) closed with a rubber stopper and aluminium cap.

Package size: 500 ml.

5.5 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Intervet Ireland Limited

7. MARKETING AUTHORISATION NUMBER(S)

VPA10996/290/001

8. DATE OF FIRST AUTHORISATION

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).