1. NAME OF THE VETERINARY MEDICINAL PRODUCT

AquaVac 6 emulsion for injection for Atlantic salmon

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 0.1 ml dose contains:

Active substances:

Infectious pancreatic necrosis virus (IPNV) serotype Sp, inactivated	≥ 1.5 ELISA units[1]
Aeromonas salmonicida subsp. s*almonicida*, inactivated	≥ 10.7 $\log_2$ ELISA units[2]
Vibrio salmonicida, inactivated	≥ 90% RPS[3]
Listonella (Vibrio) anguillarum serotype O1, inactivated	≥ 75% RPS[3]
Listonella (Vibrio) anguillarum serotype O2a, inactivated	≥ 75% RPS[3]
Moritella viscosa, inactivated	≥ 6.5 $\log_2$ ELISA units[2]

[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

Adjuvant:

Paraffin, light liquid 43 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 (*Salmo salar* L).

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), *Vibrio salmonicida* (cold-water vibriosis), *Listonella (Vibrio) anguillarum* serotype O1 and O2a (vibriosis), and *Moritella viscosa* (winter ulcer disease).

Onset of immunity: 500 degree days after vaccination for the bacterial antigens and 608 degree days after vaccination for IPNV.

Duration of immunity:
A. salmonicida and *M. viscosa*: 18 months,
L. anguillarum O1, *L. anguillarum O2a* and *V. salmonicida*: 16 months,

Infectious pancreatic necrosis virus: 4 months.

3.3 Contraindications

None.

3.4 Special warnings

Vaccinate healthy fish only.

3.5 Special precautions for use

Special precautions for safe use in the target species:
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 side effects.

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.

Other precautions:
Not applicable

3.6 Adverse events

Atlantic salmon (*Salmo salar* L):

Very common (>1 animal / 10 animals treated):	Adhesion in fish[1], Melanin accumulation in fish[1], Visible vaccine in fish, Decreased appetite[2].
Uncommon	Adhesion in fish[3].

(1 to 10 animals / 1,000 animals treated):	

[1] Oil adjuvant increases the risk of adhesions and pigmentation in the abdominal cavity. Adhesions with a Speilberg score of 1 to 3, mainly scores ≤ 2.
[2] The loss of appetite is most pronounced during the first week after vaccination and feed intake is restored within 10-12 days. Appetite loss after vaccination does not affect weight at harvest.
[3] More extensive changes (Speilberg score of 4).

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 its local representative 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.

Dosage: a single dose of 0.1 ml.
Administration: intraperitoneally along the central line, approximately 1 pelvic fin length in front of the pelvic fin base in Atlantic salmon.

Vaccination is recommended for fish above 30 grams.

Food 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.
Ensure that the recommended dose is deposited into the abdominal cavity before the needle is withdrawn.

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

Following the administration of a 2x overdose, no reactions other than those described under section 3.6 were observed.

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: QI10AL02.

Stimulates active immunity against infectious pancreatic necrosis, furunculosis, cold-water vibriosis, vibriosis and winter ulcer disease 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 the same day.

5.3 Special precautions for storage

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

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 (5000 doses).

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)

VPA10996/288/001

8. DATE OF FIRST AUTHORISATION

24/06/2022

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

10/01/2023

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).