

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

AquaVac 6 emulsion for injection for Atlantic salmon

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose of 0.1 ml contains:

Active substances:

Infectious pancreatic necrosis virus (IPNV) serotype Sp, inactivated ≥ 1.5 ELISA units¹

Aeromonas salmonicida subsp. *salmonicida*, inactivated $\geq 10.7 \log_2$ ELISA units²

Vibrio salmonicida, inactivated $\geq 90\%$ RPS³

Listonella (Vibrio) anguillarum serotype O1, inactivated $\geq 75\%$ RPS³

Listonella (Vibrio) anguillarum serotype O2a, inactivated $\geq 75\%$ RPS³

Moritella viscosa, inactivated $\geq 6.5 \log_2$ ELISA units²

¹Antigenic mass measured in the final product

²Serological response in Atlantic salmon

³RPS: relative percentage survival in a laboratory test in Atlantic salmon

Adjuvant:

Paraffin, light liquid 43 mg.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Emulsion for injection.

White to nearly white emulsion.

4. CLINICAL PARTICULARS

4.1 Target species

Atlantic salmon (*Salmo salar* L).

4.2 Indications for use, specifying the 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

4.3 Contraindications

None.

4.4 Special warnings for each target species

Vaccinate healthy fish only.

4.5 Special precautions for use

Special precautions for use in animals

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 ($\geq 17^{\circ}\text{C}$) 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 needle 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 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 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)

Oil adjuvant increases the risk of side effects after vaccination in the form of adhesions and pigmentation in the abdominal cavity. Moderate adhesions and pigmentation in the abdominal cavity are very commonly observed.

Vaccine residues occur very commonly.

Adhesions with a Speilberg score of 1 to 3 are commonly seen with most of the scores ≤ 2 .

More extensive changes (Speilberg score 4) uncommonly occur. A reduction in appetite after vaccination is very commonly observed. 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.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports)

4.7 Use during pregnancy, lactation or lay

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

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

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.

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

Following the administration of a 2x overdose, no reactions other than those described under section 4.6 were observed.

4.11 Withdrawal period(s)

Zero degree days.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Immunologicals for *Pisces*, inactivated bacterial and viral vaccines for Atlantic salmon.

ATC vet code: QI10AL02.

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

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Paraffin, light liquid
Polysorbate 80
Sorbitan monooleate
Sodium chloride
Potassium chloride
Disodium phosphate dihydrate
Potassium dihydrogen phosphate
Water for injections

6.2 Major 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: 9 months.
Shelf-life after first opening the container: use within the same day.

6.4 Special precautions for storage

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

6.5 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).

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

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

MSD Animal Health UK Limited
Walton Manor
Walton
Milton Keynes
Buckinghamshire
MK7 7AJ

8. MARKETING AUTHORISATION NUMBER

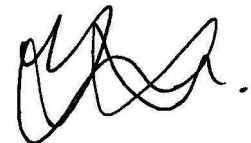
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9. DATE OF FIRST AUTHORISATION

24 May 2022

10. DATE OF REVISION OF TEXT

May 2022

A handwritten signature in black ink, consisting of several loops and a final horizontal stroke.

Approved: 24 May 2022