

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

PET Bottle

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Aquavac 6 vet emulsion for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Per dose of 0.1 ml:

Infectious pancreatic necrosis virus ≥ 1.5 ELISA units

Aeromonas salmonicida subsp. *salmonicida* $\geq 10.7 \log_2$ ELISA units

Vibrio salmonicida $\geq 90\%$ RPS

Listonella (Vibrio) anguillarum serotype O1 $\geq 75\%$ RPS

Listonella (Vibrio) anguillarum serotype O2a $\geq 75\%$ RPS

Moritella viscosa $\geq 6.5 \log_2$ ELISA units

Adjuvant:

Paraffin, light liquid

3. PACKAGE SIZE

500 ml (5000 doses)

4. TARGET SPECIES

Atlantic salmon

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Intraperitoneal use. Shake the bottle well before use.

7. WITHDRAWAL PERIODS

Withdrawal period: zero degree days.

8. EXPIRY DATE

Exp. {mm/yyyy}

Once broached use within the same day.

9. SPECIAL STORAGE PRECAUTIONS

Store and transport refrigerated. Do not freeze.

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

MSD Animal Health UK Limited

14. MARKETING AUTHORISATION NUMBERS

Vm 01708/3000

15. BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Aquavac 6 vet emulsion for injection for Atlantic salmon

2. Composition

Each 0.1 ml dose contains:

Active substances:

Infectious pancreatic necrosis virus (IPNV) serotype Sp, inactivated units ¹	≥ 1.5 ELISA
<i>Aeromonas salmonicida</i> subsp. <i>salmonicida</i> , inactivated ELISA units ²	≥ 10.7 log ₂
<i>Vibrio salmonicida</i> , inactivated	≥ 90% RPS ³
<i>Listonella (Vibrio) anguillarum</i> serotype O1, inactivated	≥ 75% RPS ³
<i>Listonella (Vibrio) anguillarum</i> serotype O2a, inactivated	≥ 75% RPS ³
<i>Moritella viscosa</i> , inactivated ELISA units ²	≥ 6.5 log ₂

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.

White to nearly white emulsion.

3. Target species

Atlantic salmon (*Salmo salar* L).

4. Indications for use

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:

<i>A. salmonicida</i> and <i>M. viscosa</i> :	18 months,
<i>L. anguillarum</i> O1, <i>L. anguillarum</i> O2a and <i>V. salmonicida</i> :	16 months,
Infectious pancreatic necrosis virus:	4 months.

5. Contraindications

None.

6. Special warnings

Special warnings:

Vaccinate healthy fish only.

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 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 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.

Fertility:

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

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.

Overdose:

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

Major incompatibilities:

Do not mix with any other veterinary medicinal product.

7. 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 (1 to 10 animals / 1,000 animals treated):
Adhesion in fish ³ .

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) occur.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder <or the local representative of the marketing authorisation holder> using the contact details at the end of this leaflet, or via your national reporting system: {national system details}.

{< > to be adjusted nationally}

8. Dosage for each species, routes and method of administration

Intraperitoneal use.

Dosage: 0.1 ml per fish.

The vaccine should be administered by intraperitoneal injection along the central line, approximately
1 pelvic fin length in front of the pelvic fin base in Atlantic salmon.

9. Advice on correct administration

Shake the bottle well before use.

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 (0.1 ml) is deposited into the abdominal cavity before the needle is withdrawn (for injection site see section above).

Standard vaccination equipment and “cradle with neck cord” can be supplied on request.

10. Withdrawal periods

Zero degree days.

11. Special storage precautions

Keep out of the sight and reach of children.

Store and transport refrigerated (2 °C – 8 °C).

Do not freeze.

Do not use this veterinary medicinal product after the expiry date which is stated on the label. The expiry date refers to the last day of that month.

Shelf life after first opening the immediate packaging: use within the same day.

12. Special precautions for disposal

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

{< > to be adjusted nationally}

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 applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Vm 01708/3000

Pack size: 500 ml (5000 doses)

15. Date on which the package leaflet was last revised

15 November 2023

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

16. Contact details

Marketing authorisation holder <and manufacturer responsible for batch release>
<and contact details to report suspected adverse reactions>:

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

<Manufacturer responsible for batch release> {to be adjusted nationally if included in
the above}

Intervet International B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
The Netherlands

<For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder>.

{< > to be adjusted nationally}

<Local representative < and contact details to report suspected adverse reactions>:>

{< > to be adjusted nationally}

17. Other information

{to be completed nationally}

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