LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Bottle

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

AquaVac 6 emulsion for injection for Atlantic salmon

2. STATEMENT OF ACTIVE SUBSTANCES

Per dose of 0.1 ml:
Infectious pancreatic necrosis virus ≥ 1.5 ELISA units
Aeromonas salmonicida subsp. *Salmonicida* ≥ 10.7 $\log_2$ ELISA units
Vibrio salmonicida ≥ 90% RPS
Listonella (Vibrio) anguillarum serotype O1 ≥ 75% RPS
Listonella (Vibrio) anguillarum serotype O2a ≥ 75% RPS
Moritella viscosa ≥ 6.5 $\log_2$ ELISA units

Adjuvant:
Paraffin, light liquid

3. PHARMACEUTICAL FORM

Emulsion for injection.

4. PACKAGE SIZE

500 ml (5 000 doses)

5. TARGET SPECIES

Atlantic salmon.

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Intraperitoneal use.
Shake the bottle well before use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period: zero degree days.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.
Accidental injection is dangerous.

10. EXPIRY DATE

EXP: {month/year}

Once broached, use within the same day.

11. SPECIAL STORAGE CONDITIONS

Store and transport refrigerated. Do not freeze.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only.
To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

16. MARKETING AUTHORISATION NUMBER

Vm 01708/5065

17. MANUFACTURER'S BATCH NUMBER

Lot: {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
AquaVac 6 emulsion for injection for Atlantic salmon

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder
MSD Animal Health UK Ltd.
Walton Manor
Walton
Milton Keynes
Buckinghamshire
MK7 7AJ

Manufacturer responsible for batch release
Intervet International B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
The Netherlands

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

AquaVac 6 emulsion for injection for Atlantic salmon

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Each dose of 0.1 ml contains:

Active substances:
Infectious pancreatic necrosis virus (IPNV) serotype Sp, inactivated: ≥ 1.5 ELISA units[1]
Aeromonas salmonicida subsp. *salmonicida*, 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

4. INDICATION(S)

For active immunisation of Atlantic salmon to reduce mortality from 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.

5. CONTRAINDICATIONS

None.

6. ADVERSE REACTIONS

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)

If you notice any side effects, even those not already listed in this leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

7. TARGET SPECIES

Atlantic salmon (*Salmo salar* L).

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Intraperitoneal use.
Shake the bottle well before 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

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 8.).
Standard vaccination equipment and “cradle with neck cord” can be supplied on request.

10. WITHDRAWAL PERIOD

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.
Shelf-life after first opening the container: use within the same day.

12. SPECIAL WARNING(S)

Special warnings for each target species:
Vaccinate healthy fish only.

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 (≥ 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 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.

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 (symptoms, emergency procedures, antidotes):
Following the administration of a 2x overdose, no reactions other than those described in section 6 were observed.

Incompatibilities:
Do not mix with any other veterinary medicinal product.

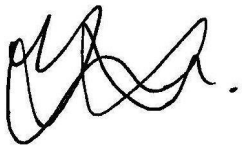
13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

Pack size: 500 ml (5 000 doses)



Approved: 08 August 2022