ANNEX III
LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Bottle

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

AQUAVAC PD
Emulsion for injection, for Atlantic salmon.

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Per dose of 0.1 ml vaccine:
Inactivated salmon pancreas disease virus (SPDV) strain F93-125: ≥ 80% RPP
Light liquid paraffin 43 mg

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.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Withdrawal period: zero degree days.

9. SPECIAL WARNING(S), IF NECESSARY

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

10. EXPIRY DATE

EXP {month/year}
Once broached use within the same day.

11. SPECIAL STORAGE CONDITIONS

Store in a refrigerator.
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
MK7 7AJ

16. MARKETING AUTHORISATION NUMBER(S)

Vm 01708/4614

17. MANUFACTURER'S BATCH NUMBER

<Batch> <Lot> <BN> {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET FOR:
AQUAVAC PD 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 Limited
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 PD emulsion for injection for Atlantic salmon.

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

Per dose of 0.1 ml vaccine:

Active substance:
Inactivated salmon pancreas disease virus (SPDV) strain F93-125 ≥ 80% RPP[1]

Adjuvant:
Light liquid paraffin, 43 mg.

[1]RPP: relative percentage protection in a laboratory test in Atlantic salmon

Emulsion for injection. White to slightly pink.

4. INDICATION(S)

For active immunisation of Atlantic salmon to reduce viraemia, heart lesions and mortality due to infection with SPDV (pancreas disease).

Onset of immunity: 500 degree days.

Duration of immunity:

Reduction of viraemia: 10 months
Reduction of heart lesions: 12 months
Reduction of mortality: not established.

5. CONTRAINDICATIONS

None.

6. ADVERSE REACTIONS

In the abdominal cavity, vaccine residues and mild melanisation that is possible to remove were very commonly observed in studies. Visceral adhesions were observed; Speilberg scores of 1 and 2 were very commonly observed and score 3 was commonly observed in studies.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals displaying adverse reactions during the course of one treatment)
- common (more than 1 but less than 10 animals in 100 animals)
- uncommon (more than 1 but less than 10 animals in 1,000 animals)
- rare (more than 1 but less than 10 animals in 10,000 animals)
- very rare (less than 1 animal in 10,000 animals, including isolated reports).

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 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.
Dose: 0.1 ml per fish.

Vaccination is recommended for fish above 30 grams.

Route of administration: intraperitoneal injection along the central line, approximately 1 pelvic fin length in front of the pelvic fin base.

9. ADVICE ON CORRECT ADMINISTRATION

Food should be withheld for sufficient time to ensure emptying of the gut prior to vaccination. The fish should be anaesthetised before vaccination. The length and the diameter of the needle used should be adapted to the size of the fish. Ensure the recommended dose is deposited into the abdominal cavity before the needle is withdrawn.

Shake the bottle well before use without generating air bubbles.

10. WITHDRAWAL PERIOD

Zero degree days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Store in a refrigerator (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

Do not use in fish during smoltification.
Do not vaccinate below 2.5°C or above 17°C.
Vaccination at high water temperature (≥ 17°C) may increase adverse reactions.
Incorrect vaccination, stress and poor hygiene may lead to increased adverse reactions.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Personal protective equipment consisting of e.g. needle protector should be used when handling the product.
In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the 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:
The possible effects of vaccination on reproduction have not been investigated, therefore vaccination of breeding stock is not recommended.

Interaction with other medicinal products and other forms of interaction:
Safety and efficacy data are available which demonstrate that this vaccine can be administered at least 240 degree days or at least 3 weeks before the administration of the company's multivalent oil adjuvanted vaccine Norvax Minova 6 where authorised for use in Atlantic salmon. Aquavac PD and Norvax Minova 6 should not be administered simultaneously.

After concurrent use with Norvax Minova 6, in the abdominal cavity, vaccine residues and melanisation that is possible to remove were very commonly observed in studies. Unremovable melanisation was commonly observed in studies. Visceral adhesions were observed; Speilberg scores of 1 to 3 were very commonly observed and score 4 was uncommonly observed in studies.

No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product, except the product mentioned above. 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)
No data available; overdose studies are not required for inactivated vaccines.

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

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

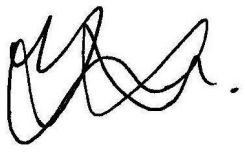
Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

June 2020

15. OTHER INFORMATION

For animal treatment only.
Pack size: 500 ml (5,000 doses).



Approved: 10 June 2020