SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

AquaVac PD3 emulsion for injection for Atlantic salmon

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Per dose of 0.1 ml vaccine:

Active substance(s):
Salmon pancreas disease virus (SPDV) strain F93-125, ≥ 75% RPP[1]
Infectious pancreatic necrosis virus (IPNV), ≥ 1.5 ELISA units[2]
Aeromonas salmonicida subsp. *salmonicida*, ≥ 80% RPS_{60}[3]

[1] RPP: relative percentage protection in a laboratory test in Atlantic salmon
[2] Antigenic mass measured in the final product
[3] RPS: relative percentage survival at 60% control mortality in a laboratory test in Atlantic salmon

Adjuvant:
Light liquid paraffin, 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 clinical signs (heart lesions and pancreas lesions), viremia, viral shedding and mortality from infection with SPDV (Pancreas disease) and to reduce mortality from infections with IPNV (Infectious pancreatic necrosis) and *Aeromonas salmonicida* subsp. *salmonicida* (furunculosis).

Onset of immunity: 500 degree days after vaccination for SPDV and *Aeromonas salmonicida* and 540 degree days after vaccination for IPNV.

Duration of immunity: demonstrated at 15 months post vaccination for SPDV and at 16 months post vaccination for *Aeromonas salmonicida*. Protection against mortality due to IPNV infection has been demonstrated at 4 months post vaccination in the field.

4.3 Contraindications

None.

4.4 Special warnings for each target species

Vaccinate healthy animals only.

4.5 Special precautions for use

Special precautions for use in animals
Do not use in fish during smoltification.
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 e.g. needle protector should be used when handling the veterinary medicinal 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)

After vaccination melanisation and vaccine residues are very commonly observed in the abdominal cavity. Visceral adhesion may be observed; during the fresh water phase up to sea transfer phase slight to moderate adhesions (corresponding to Speilberg scores 1 – 3) very commonly occur while the occurrence of major adhesions (corresponding to Speilberg score of 4) is uncommon.
During the sea water phase mild adhesions (corresponding to Speilberg scores 1 – 2) are very common and moderate adhesions (corresponding to Speilberg score 3) are common.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reactions)
- 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

Fertility:
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

Dose: 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. Shake the bottle well before use.

Vaccination is recommended for fish above 30 grams.

Food should be withheld for sufficient time (at least 48 hours) to ensure emptying of the gut 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

After administration of a double dose more vaccine residues can be observed, but no increase in local reactions is observed compared to single dose administration.

4.11 Withdrawal period(s)

Zero degree days.

5. IMMUNOLOGICAL PROPERTIES

The product stimulates active immunity against pancreas disease, infectious pancreatic necrosis, and furunculosis.

Pharmacotherapeutic group: immunologicals for Pisces, inactivated viral and inactivated bacterial vaccines for Atlantic salmon.
ATCvet code: QI10AL.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Light liquid paraffin
Polysorbate 80
Sorbitan monooleate
Phosphate buffered saline

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: 19 months
Shelf-life after first opening the immediate packaging: use within 1 working day

6.4. Special precautions for storage

Store in a refrigerator (2 - 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 (5,000 doses).

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the 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

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

As represented by the national company

8. MARKETING AUTHORISATION NUMBER(S)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation:
Date of last renewal:

10. DATE OF REVISION OF THE TEXT

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Bottle of 500 ml (PET)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

AquaVac PD3 emulsion for injection for Atlantic salmon

2. STATEMENT OF ACTIVE SUBSTANCES

Per dose of 0.1 ml vaccine:
Salmon pancreas disease virus (SPDV) ≥ 75% RPP
Infectious pancreatic necrosis virus (IPNV) ≥ 1.5 ELISA units
Aeromonas salmonicida subsp. *salmonicida* ≥ 80% RPS_{60}

Light liquid paraffin, 43 mg

3. PHARMACEUTICAL FORM

Emulsion for injection.

4. PACKAGE SIZE

500 ml (5000 doses)

5. TARGET SPECIES

Atlantic salmon.

6. INDICATION(S)

Vaccine against pancreas disease, infectious pancreatic necrosis and furunculosis.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.
Intraperitoneal use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period(s): 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 1 working 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

16. MARKETING AUTHORISATION NUMBER(S)

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
AquaVac PD3 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 and 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 PD3 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 substances:
Salmon pancreas disease virus (SPDV) strain F93-125 ≥ 75% RPP[1]
Infectious pancreatic necrosis virus (IPNV) ≥ 1.5 ELISA units[2]
Aeromonas salmonicida subsp. *salmonicida* ≥ 80% RPS_{60}[3]

Light liquid paraffin, 43 mg

[1] RPP: relative percentage protection in a laboratory test in Atlantic salmon
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Emulsion for injection.

4. INDICATION(S)

For active immunisation of Atlantic salmon to reduce clinical signs (heart lesions and pancreas lesions), viremia, viral shedding and mortality from infection with SPDV (Pancreas disease) and to reduce mortality from infections with IPNV (Infectious pancreatic necrosis) and *Aeromonas salmonicida* subsp. *salmonicida* (furunculosis).

Onset of immunity: 500 degree days after vaccination for SPDV and *Aeromonas salmonicida* and 540 degree days after vaccination for IPNV.

Duration of immunity: demonstrated at 15 months post vaccination for SPDV and at 16 months post vaccination for *Aeromonas salmonicida*. Protection against mortality due to IPNV infection has been demonstrated at 4 months post vaccination in the field.

5. CONTRAINDICATIONS

None.

6. ADVERSE REACTIONS

After vaccination melanisation and vaccine residues are very commonly observed in the abdominal cavity. Visceral adhesion may be observed; during the fresh water phase up to sea transfer phase slight to moderate adhesions (corresponding to Speilberg scores 1 – 3) very commonly occur while the occurrence of major adhesions (corresponding to Speilberg score of 4) is uncommon.
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- 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 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

Dose: 0.1 ml per fish.

Route of administration: intraperitoneal injection in Atlantic salmon. Correct site of injection is along the central line, approximately 1 pelvic fin length in front of the pelvic fin base. Shake the bottle well before use.

9. ADVICE ON CORRECT ADMINISTRATION

Vaccination is recommended for fish above 30 grams.
Food should be withheld for sufficient time (at least 48 hours) to ensure emptying of the gut 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.

10. WITHDRAWAL PERIOD(S)

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 1 working day.

12. SPECIAL WARNING(S)

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

Special precautions for use in animals:
Do not use in fish during smoltification.
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 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 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):
After administration of a double dose more vaccine residues can be observed, but no increase in local reactions is observed compared to single dose administration.

Incompatibilities
Do not mix with any other veterinary medicinal product.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

Pack size: 500 ml (5000 doses)