1. NAME OF THE VETERINARY MEDICINAL PRODUCT

AquaVac PD3 emulsion for injection for Atlantic salmon

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose of 0.1 ml contains:

Active substances:
Salmon pancreas disease virus (SPDV), strain F93-125, inactivated ≥ 75% RPP[1]
Infectious pancreatic necrosis virus (IPNV), inactivated ≥ 1.5 ELISA units[2]
Aeromonas salmonicida, subsp. *salmonicida*, inactivated ≥ 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_{60}: relative percentage survival at 60% control mortality in a laboratory test in Atlantic salmon

Adjuvant:
Light liquid paraffin, 43 mg

Excipients:

Qualitative composition of excipients and other constituents
Polysorbate 80
Sorbitan monooleate
Phosphate buffered saline

White to nearly white emulsion.

3. CLINICAL INFORMATION

3.1 Target species

Atlantic salmon.

3.2 Indications for use for each 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.

3.3 Contraindications

None.

3.4 Special warnings

Vaccinate healthy animals only.

3.5 Special precautions for use

Special precautions for safe use in the target species:
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 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 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.

3.6 Adverse events

Atlantic salmon:

Very common (>1 animal / 10 animals treated):	Melanin accumulation in fish[1], visible vaccine in fish[1], adhesion in fish[2].
Common (1 to 10 animals / 100 animals treated):	Adhesion in fish[3].
Uncommon (1 to 10 animals / 1,000 animals treated):	Adhesion in fish[4].

[1] Observed in the abdominal cavity.
[2] Speilberg scores 1-3 during the fresh water phase up to sea transfer, Speilberg scores 1-2 during the sea water phase.
[3] Speilberg score 3 during the sea water phase.
[4] Speilberg score 4 during the fresh water phase up to sea transfer.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder <or its local representative> or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

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

3.8 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.

3.9 Administration routes and dosage

Intraperitoneal use.

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.

3.10 Symptoms of overdose (and where applicable, emergency procedures and 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.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Zero degree days.

4. IMMUNOLOGICAL INFORMATION

4.1 ATCvet code: QI10AL.

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

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product.

5.2 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.

5.3 Special precautions for storage

Store in a refrigerator (2 °C – 8 °C).
Do not freeze.

5.4 Nature and composition of immediate packaging

Bottles of polyethylene terephthalate (PET) closed with a rubber stopper and aluminium cap.

Pack size:
500 ml (5,000 doses).

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

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

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 national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

{Name}

7. MARKETING AUTHORISATION NUMBER(S)

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: {DD/MM/YYYY}.

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

{MM/YYYY}

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

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

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

2. STATEMENT OF ACTIVE SUBSTANCES

Each dose of 0.1 ml contains:
Salmon pancreas disease virus (SPDV), strain F93-125, inactivated ≥ 75% RPP
Infectious pancreatic necrosis virus (IPNV), inactivated ≥ 1.5 ELISA units
Aeromonas salmonicida, subsp. *salmonicida*, inactivated ≥ 80% RPS_{60}

3. PACKAGE SIZE

500 ml (5,000 doses)

4. TARGET SPECIES

Atlantic salmon

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Intraperitoneal use.

7. WITHDRAWAL PERIODS

Withdrawal period: zero degree days.

8. EXPIRY DATE

Exp. {mm/yyyy}
Once broached use within 1 working day.

9. SPECIAL STORAGE PRECAUTIONS

Store in a refrigerator.
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

{Name or company name or logo name of the marketing authorisation holder}

14. MARKETING AUTHORISATION NUMBERS

15. BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

AquaVac PD3 emulsion for injection for Atlantic salmon

2. Composition

Each dose of 0.1 ml contains:

Active substances:
Salmon pancreas disease virus (SPDV), strain F93-125, inactivated ≥ 75% RPP[1]
Infectious pancreatic necrosis virus (IPNV), inactivated ≥ 1.5 ELISA units[2]
Aeromonas salmonicida, subsp. *salmonicida*, inactivated ≥ 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_{60}: relative percentage survival at 60% control mortality in a laboratory test in Atlantic salmon

Adjuvant:
Light liquid paraffin, 43 mg

White to nearly white emulsion.

3. Target species

Atlantic salmon.

4. Indications for use

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. Special warnings

Special warnings:
Vaccinate healthy animals only.

Special precautions for safe use in the target species:
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 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 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.

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:
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.

Major incompatibilities:
Do not mix with any other veterinary medicinal product.

7. Adverse events

Atlantic salmon:

Very common (>1 animal / 10 animals treated):	Melanin accumulation in fish[1], visible vaccine in fish[1], adhesion in fish[2].
Common (1 to 10 animals / 100 animals treated):	Adhesion in fish[3].
Uncommon (1 to 10 animals / 1,000 animals treated):	Adhesion in fish[4].

[1] Observed in the abdominal cavity.

[2] Speilberg scores 1-3 during the fresh water phase up to sea transfer, Speilberg scores 1-2 during the sea water phase.
[3] Speilberg score 3 during the sea water phase.
[4] Speilberg score 4 during the fresh water phase up to sea transfer.

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}.

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

Intraperitoneal use.

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 periods

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. The expiry date refers to the last day of that month.

Shelf life after first opening the immediate packaging: use within 1 working day.

12. Special precautions for disposal

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

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 or pharmacist 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

Pack size:
500 ml (5,000 doses)

15. Date on which the package leaflet was last revised

{MM/YYYY}

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>:

<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

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

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

17. Other information

{to be completed nationally}