Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

AQUAVAC PD emulsion for injection for Atlantic salmon

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Per dose of 0.1 ml vaccine:

Active substance:

Inactivated salmon pancreas disease virus (SPDV) strain F93-125 = 80% RPP[1]

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

Adjuvant:

Light liquid paraffin 43 mg

Excipients:

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Emulsion for injection. White to slightly pink.

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 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.

4.3 Contraindications

None.

4.4 Special warnings for each target species

Vaccinate healthy fish only.

4.5 Special precautions for use

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.

4.6 Adverse reactions (frequency and seriousness)

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).

4.7 Use during pregnancy, lactation or lay

Fertility:
The possible effects of vaccination on reproduction have not been investigated, therefore vaccination of breeding stock is not recommended.

4.8 Interaction with other medicinal products and other forms of interactions

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 oil adjuvanted multivalent 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 mild 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.

4.9 Amounts to be administered and administration route

For intraperitoneal use.

Dose:a single dose of 0.1 ml.
Administration route:intraperitoneal injection along the central line, approximately 1 pelvic fin length in front of the pelvic fin base.

Vaccination is recommended for fish above 30 grams.

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.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

No data available; overdose studies are not required for inactivated vaccines.

4.11 Withdrawal period(s)

Zero degree days.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: immunologicals for Pisces; Atlantic salmon; inactivated viral vaccines; Salmon pancreas disease virus (SPD).
ATCvet code: QI10AA01.

The product stimulates active immunity against pancreas disease in Atlantic salmon.

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

6.4 Special precautions for storage

Store in a refrigerator (2°C - 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. Pack size: 500 ml (5,000 doses).

6.6 Special precautions for the disposal of unused veterinary medicinal products 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 Ireland Limited
Magna Drive
Magna Business Park, Citywest Road
Dublin 24
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA10996/281/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 14 July 2017

10 DATE OF REVISION OF THE TEXT

May 2020