

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ALPHA JECT micro 1 PD emulsion for injection for Atlantic salmon

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 dose (0.05 ml) contains:

Active substance:

Formaldehyde inactivated culture of:

Salmon Pancreas Disease Virus (SPDV) strain AL V405

RPS_{end}^a ≥ 80 %

^aRPS_{end} = Relative percentage survival at end control mortality in a laboratory test in Atlantic salmon

Adjuvant:

Paraffin, light liquid (mineral oil): 23 mg

Excipients:

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Emulsion for injection.

White to cream coloured emulsion.

4. CLINICAL PARTICULARS

4.1 Target species

Atlantic salmon (*Salmo salar* L) with a minimum weight of 28 g.

4.2 Indications for use, specifying the target species

For active immunisation of Atlantic salmon to reduce mortality, lesions in the heart and pancreas, and impaired growth caused by Pancreas Disease (PD).

Onset of immunity: 516 degree days.

Duration of immunity: at least 12 months.

4.3 Contraindications

None.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

Fish with clinical symptoms of disease should not be vaccinated. Vaccination should preferably be performed at water temperatures of 15 °C or lower.

Avoid vaccination during smoltification.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

The use of needle guards is recommended in order to reduce the risk of accidental self-injection.

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 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)

Melanisation and vaccine residues are very commonly observed in the abdominal cavity after vaccination. Mild visceral adhesions (corresponding to Speilberg scores 1 – 2) are very common, moderate adhesions (corresponding to Speilberg scores 3) are common, while the occurrence of severe adhesions (corresponding to Speilberg score ≥ 4) is very rare.

Spinal deformities of the so-called “cross-stitch vertebrae” type, have been commonly reported after the use of Alpha Ject micro 1 PD, primarily in fish put at sea in the autumn (S0-generation). These deformities are believed to have multifactorial causes and are possibly linked to the vaccine’s PD component. However, a causal relationship has not been proven.

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).

4.7 Use during pregnancy, lactation or lay

Vaccination of broodfish is not recommended and should be subject to a risk benefit evaluation of the prescribing veterinarian/fish health biologist.

4.8 Interaction with other medicinal products and other forms of interaction

Safety and efficacy data are available which demonstrate that this vaccine can be administered simultaneously with PHARMAQ's oil adjuvanted multivalent vaccines containing the following antigens: *Aeromonas salmonicida*, *Listonella anguillarum* O1 and O2a, *Vibrio salmonicida*, *Moritella viscosa* and Infectious Pancreas Necrosis Virus (IPNV). The vaccines are administered intraperitoneally either simultaneously (one injection) or in immediate succession (two injections) while fish are anaesthetised.

No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product except the products 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

Posology

A single dose of 0.05 ml per fish.

Administration route

The vaccine will be administered by intraperitoneal (i.p) injection. The fish should be anaesthetised prior to injection. It is recommended to starve the fish for a minimum of 48 hours before vaccination.

The vaccine should be left to slowly reach 15 – 20 °C by keeping it at room temperature. The vaccine should not be used if the vaccine shows signs of a brownish water phase in the bottom of the container. Contact the distributor for further advice. The vaccine should be well shaken prior to use by squeezing and shaking for approx. 2 minutes. Only administer if the vaccine appears as a homogenous, white to cream coloured emulsion.

To reduce the risk of adverse reactions, it is important to deposit the entire dose into the abdominal cavity. The injection needle used should have appropriate length to penetrate the abdominal wall by 1 – 2 mm. The entire needle should be inserted into the midline about one fin length anterior to the base of the pelvic fin.

The injection devices used for vaccination, i.e. automatic vaccination machines or manual syringes, must be designed and suitable for administration of the recommended dose volume in the target species. The devices must be operated by trained personnel and should be calibrated according to the manufacturers' recommendation prior to use. Special care should be taken to ensure air is removed from the injection equipment (chambers and tubes) prior to vaccination. Regular dose controls (number of injections per bag) are recommended.

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

Administration of the vaccine in 0.1 ml (double dose) shows no other adverse reactions than those described in section 4.6.

4.11 Withdrawal period

Zero degree days

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Inactivated viral vaccine.
ATC vet code: QI10AA 01

Stimulates development of active immunity against Pancreas Disease. Reduction of mortality during clinical outbreaks of Pancreas Disease has been documented up to 15 months post vaccination under field conditions.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sorbitan oleate
Polysorbate 80

6.2 Major incompatibilities

Do not mix with any other veterinary medicinal products.

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: 10 hours.

6.4. Special precautions for storage

Store and transport refrigerated (2 °C – 8 °C).
Do not freeze.
Protect from light.

6.5 Nature and composition of immediate packaging

Bags made of a multilayer plastic foil. The giving port is closed with a rubber stopper. The bag is packed in a zip-lock bag or cardboard box.

Pack size:

Zip-lock bag: 250 ml and 500 ml

Cardboard box: 10 x 500 ml

Not all pack sizes may be marketed.

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

PHARMAQ AS
Skogmo Industriområde
Industrivegen 50
7863 Overhalla
Norway

8. MARKETING AUTHORISATION NUMBER

To be completed nationally

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: *To be completed nationally*

Date of last renewal: *To be completed nationally*

10 DATE OF REVISION OF THE TEXT

To be completed nationally

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.