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:
Salmon pancreas disease virus, strain AL V405, inactivated $RPS_{end} \geq 80$ %

RPS_{end} : Relative percentage survival at end control mortality in a laboratory test in Atlantic salmon

Adjuvant:
Paraffin, light liquid (mineral oil): 23 mg

Excipients:

Qualitative composition of excipients and other constituents
Sorbitan oleate
Polysorbate 80

White to cream coloured emulsion.

3. CLINICAL INFORMATION

3.1 Target species

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

3.2 Indications for use for each 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.

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:
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 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):	Adhesion (Speilberg score 1-2)[1], melanin accumulation[1], visible vaccine[1]
Common (1 to 10 animals / 100 animals treated):	Adhesion (Speilberg score 3)[1], fish body deformity[2]
Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Adhesion (Speilberg score ≥ 4)[1]

[1] In the abdominal cavity
[2] Spinal deformities of the so-called “cross-stitch vertebrae” type, 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.

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 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

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

3.8 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.

3.9 Administration routes and dosage

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.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

Administration of the vaccine in 0.1 ml (double dose) shows no other adverse reactions than those described in section 3.6.

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 : 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.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other veterinary medicinal products.

5.2 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.

5.3 Special precautions for storage

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

5.4 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 sizes:
Zip-lock bag: 250 ml and 500 ml
Cardboard box: 10 x 500 ml

Not all pack sizes may be marketed.

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

Pharmaq AS

7. MARKETING AUTHORISATION NUMBER(S)

VPA10804/003/001

8. DATE OF FIRST AUTHORISATION

04/12/2015

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

01/07/2025

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).