

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Label for injection bag

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ALPHA JECT micro 1 PD
Emulsion for injection for Atlantic salmon

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

1 dose (0.05 ml) contains:
Formaldehyde inactivated culture of:
Salmon Pancreas Disease Virus (SPDV) strain AL V405 RPS_{end} ≥ 80 %

Paraffin, light liquid: 23 mg

3. PHARMACEUTICAL FORM

Emulsion for injection

4. PACKAGE SIZE

250 ml
500 ml

5. TARGET SPECIES

Atlantic salmon (*Salmo salar* L)

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Intraperitoneal injection.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Withdrawal period: Zero degree days.

9. SPECIAL WARNING(S), IF NECESSARY

Accidental self-injection is dangerous.

10. EXPIRY DATE

EXP: month/year
Once broached use within: 10 hours.

11. SPECIAL STORAGE CONDITIONS

Store and transport refrigerated.
Do not freeze.
Protect from light

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

Pharmaq AS
Skogmo Industriområde
Industrivegen 50
7863 Overhalla
Norway

16. MARKETING AUTHORISATION NUMBER

Vm 21714/3000

17. MANUFACTURER'S BATCH NUMBER

Batch:

PACKAGE LEAFLET:

ALPHA JECT micro 1 PD 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:

Pharmaq AS
Skogmo Industriområde
Industrivegen 50
7863 Overhalla
Norway

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

ALPHA JECT micro 1 PD emulsion for injection for Atlantic salmon

3. STATEMENT OF THE ACTIVE SUBSTANCES AND OTHER INGREDIENTS

1 dose (0.05 ml) contains:

Active substance:

Formaldehyde inactivated culture of:

Salmon Pancreas Disease Virus (SPDV) strain AL V405 $RPS_{end}^a \geq 80\%$

^a 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: Sorbitan oleate, Polysorbate 80

Emulsion for injection. White to cream coloured emulsion.

4. INDICATION

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.

5. CONTRAINDICATIONS

None

6. ADVERSE REACTIONS

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)

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) with a minimum weight of 28 g.

8. DOSAGE FOR EACH SPECIES, ROUTE AND METHOD OF ADMINISTRATION

Dosage

A single dose of 0.05 ml per fish with a minimum weight of 28 g.

Administration route

The vaccine should be administered by intraperitoneal (i.p) injection into the midline about one fin length anterior to the base of the pelvic fin.

9. ADVICE ON CORRECT ADMINISTRATION

The vaccine should be left to slowly reach 15 – 20 °C by keeping it at room temperature. 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, cream coloured emulsion.

The fish should be anaesthetised prior to injection. It is recommended to starve the fish for a minimum of 48 hours before vaccination.

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 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.

10. WITHDRAWAL PERIOD

Zero degree days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Store and transport refrigerated (2 °C – 8 °C).

Do not freeze.

Protect from light.

Do not use this veterinary medicinal product after the expiry date which is stated on the label after "EXP/Utløpsdato".

Shelf life after first opening the container: 10 hours

Do not use if the vaccine shows signs of a brownish water phase in the bottom of the container before shaking. Contact the manufacturer for further advice.

12. SPECIAL WARNINGS

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 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 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 ischemic 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:

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

Interaction with other medicinal products and other forms of interaction:

Safety and efficacy data are available which demonstrate that this vaccine can be administered 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.

Overdose (symptoms, emergency procedures, antidotes):

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

Incompatibilities:

Do not mix with any other veterinary medicinal products.

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

Ask your veterinarian/fish health biologist how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

June 2021

15. OTHER INFORMATION

Reduction of mortality during clinical outbreaks of Pancreas Disease has been documented for up to 15 months post vaccination under field conditions.

Injection bags made of a multilayer plastic foil. The giving port is closed with a rubber stopper.

Pack size: 250 ml and 500 ml

Not all pack sizes may be marketed.

Approved 22 July 2021

A handwritten signature in black ink, appearing to read "A. Hunter.", is positioned below the approval date.