PACKAGE LEAFLET

1. Name of the veterinary medicinal product

ALPHA JECT micro 1 PD emulsion for injection for Atlantic salmon

2. 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.

White to cream coloured emulsion.

3. Target species

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

4. Indications for use

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. Special warnings

Special warnings:
Vaccinate healthy animals only.

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.

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

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

7. 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 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 using the contact details at the end of this leaflet, or via your national reporting system at:

Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine

e-mail: adverse.events@vmd.gov.uk

8. Dosage for each species, routes 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. 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. 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 periods

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.
Shelf life after first opening the immediate packaging: 10 hours.

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 fish health biologist 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

Vm 21714/3000
Vm 21714/5000

Pack sizes:
Zip-lock bag with 1 x 250 ml or 500 ml vaccine bag, or cardboard box with 10 x 500 ml vaccine bag.

Not all pack sizes may be marketed.

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

16. Contact details

Marketing authorisation holder, manufacturer responsible for batch release and contact details to report suspected adverse events:
PHARMAQ AS
Skogmo Industriområde
Industrivegen 50
7863 Overhalla
Norway
Tel: +47 23 29 85 00
E-mail: phq.phvig@zoetis.com

17. Other information

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