PACKAGE LEAFLET:
ALPHA JECT micro 6~~,~~ 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
7863 Overhalla
Norway

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

ALPHA JECT micro 6~~,~~ 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 cultures of:

Aeromonas salmonicida subsp. *salmonicida*	RPS ≥ 70
*Listonella anguillarum** serotype O1	RPS ≥ 75
*Listonella anguillarum** serotype O2a	RPS ≥ 75
Vibrio salmonicida	RPS ≥ 90
Moritella viscosa	RPS ≥ 60
Infectious Pancreatic Necrosis Virus serotype Sp	0.2 AU

RPS: Relative Percentage Survival in challenge studies on Atlantic salmon.
AU: Antigenicity Units (measure of the quantity of virus antigen).
* *Listonella anguilllarum* is synonymous with *Vibrio anguillarum.*

Adjuvant:
Paraffin, light liquid (mineral oil).

Other excipients:
Sorbitan oleat, Polysorbat 80 and purified water ~~(sterilised)~~.

Emulsion for injection. White to cream coloured.

4. INDICATIONS

For active immunisation of Atlantic salmon to reduce clinical signs and mortality ~~of diseases~~ caused by infections with *Aeromonas salmonicida* (furunculosis), *Vibrio salmonicida* (coldwater vibriosis), *Listonella anguillarum* serotype O1and O2a (vibriosis), *Moritella viscosa* (winter sore) and IPNV (infectious pancreatic necrosis).

Onset of immunity: 520 degree days post vaccination for the bacterial antigens and 600 degree days post vaccination for IPNV.

Duration of immunity: At least 1 year for the bacterial antigens and at least 5.5 months for IPNV.

5. CONTRAINDICATIONS

None

6. ADVERSE REACTIONS

The frequency of adverse reactions observed after vaccination in laboratory studies and field trails:

Very common: Melanisation in the abdominal cavity
Mild visceral adhesions (Speilberg score 1 – 2)
Common: Moderate visceral adhesions (Speilberg score 3)
Very rare: Serious visceral adhesions (Speilberg score ≥ 4)

The majority of the adhesions caused by vaccination can be removed manually and do not normally result in downgrading of the fish at slaughter.

The extent of the adverse reactions will depend on hygiene, vaccination technique, fish size and water temperature the first 6-12 weeks after vaccination.

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/fish health biologist.

7. TARGET SPECIES

Atlantic salmon (*Salmo salar*) of a minimum weight of 25 g.

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

Intraperitoneal use.

Dosage
The recommended dose is 0.05 ml per fish.

Administration route
The vaccine ~~will~~ should be administered by intraperitoneal (i.p) injection into the midline about one fin length anterior to the base of the pelvic fin.
It is recommended to starve the fish for a minimum of 48 hours before vaccination.
The fish should be anaesthetised prior to injection.

9. ADVICE ON CORRECT ADMINISTRATION

To reduce the risk of adverse reactions, it is important to deposit the entire dose in the abdominal cavity. The injection needle used should have appropriate length to penetrate the abdominal wall and 1 – 2 mm into the abdominal cavity.

~~The~~ Let the vaccine ~~should be left to~~ slowly reach 15 – 20°C by keeping it at room temperature.
~~The vaccine should be well shaken~~ Ensure a homogenous emulsion prior to use by squeezing and shaking the vaccine bag for approx. 2 minutes.
Only administer the vaccine if it~~the vaccine~~ appears as a homogenous, white to cream coloured emulsion after shaking. 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 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 are recommended.

The vaccination equipment should be thoroughly cleaned / sterilized before use.

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.

Shelf life after first opening the container: 10 hours

12. SPECIAL WARNINGS

Special precautions for use in animals:
Do not vaccinate fish with clinical signs of disease.
Vaccination should preferably be performed at water temperatures of 15°C or below.
Do not vaccinate at water temperatures below 1°C or above 18°C.
Avoid vaccination during smoltification.

Due to handling, vaccination may be followed by a temporary reduction in appetite.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
People with known hypersensitivity to fish vaccines should avoid contact with the veterinary medicinal product.

Protective equipment consisting of guarded needles should be used during manual vaccination to reduce the risk of accidental self-injection.

Ensure that the method of fixation and handling of the fish minimises the risk of accidental self-injection. Repeated self-injections may aggravate the adverse effects or ~~cause~~ increase the risk of anaphylactic shock.

This veterinary medicinal product contains mineral oil. Accidental 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.

Fertility:
Effects of vaccinating broodfish with this veterinary medicinal product has not been investigated.
Vaccination of broodfish should only be done according~~subjected~~ to a benefit-risk ~~benefit~~ assessment~~evaluation~~ by~~of~~ the responsible~~prescribing~~ veterinarian/fish health biologist.

Interaction with other medicinal products and other forms of interaction:
No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product. 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):
~~A~~Following administration of 0.1 ml of the vaccine ~~in 0.1 ml~~ (double dose) ~~shows~~ no other adverse reactions than those described in section "Adverse r~~R~~eactions" were seen.

Incompatibilities:
Do not mix with any other veterinary medicinal product.

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

Ask your veterinary surgeon or 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

[To be completed nationally]~~.~~

15. OTHER INFORMATION

250 ml or 500 ml bag~~s~~ of multilayer plastic foil. The giving port is closed with a sealed rubber stopper.

Pack sizes:
250 ml and 500 ml
Not all pack sizes may be marketed.

For animal treatment only.
To be supplied only on veterinary prescription.

For any information about this veterinary medicinal product, please contact:
PHARMAQ AS, Postboks 267 Skøyen, 0213 Oslo, Norway