PACKAGE LEAFLET

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

PHARMAQ AS
Skogmo Industriområde
N-7863 Overhalla, Norway

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

ALPHA JECT 3000
Emulsion for injection for Atlantic salmon

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Active substance(s):
1 dose (0.1 ml) contains:
Formaldehyde inactivated bacteria cultures of:

Aeromonas salmonicida subsp. s*almonicida;* AL 2017	*RPS $\geq$ 80 (Ph. Eur.)
Listonella anguillarum serotype O1; AL 112	*RPS $\geq$ 75 (Ph. Eur.)
Listonella anguillarum serotype O2a; AL 104	*RPS $\geq$ 75 (Ph. Eur.)

Adjuvant:
Liquid paraffin

White to cream coloured homogeneous emulsion when shaken.

*RPS: Relative Percent Survival: The biological activity of one dose is given as RPS_{60} specified for each antigen according to the respective Ph. Eur. monograph, defined by the quotation: [1-(% mortality vaccinated fish/60% mortality in control fish)] x 100.

4. INDICATION(S)

Reduction of mortality by the diseases caused by *Aeromonas salmonicida* (furunculosis) and *Listonella anguillarum* serotype O1 and O2a (vibriosis) in Atlantic salmon.

The onset of immunity occurs 450 degree days after the vaccination.

5. CONTRAINDICATIONS

None

6. ADVERSE REACTIONS

Adverse reactions in the form of visceral adhesions and pigmentation occur. All vaccinated fish is expected to develop some degree of undesirable effects compared to fish not vaccinated. The severity of the adhesions and pigmentation varies. Pigmentation on the viscera occurs frequently, but pigmentation in the muscle rarely occurs. In a small scale study with side effects evaluation in a limited number of fish, an adhesion score of 3 or higher on the Speilberg scale was seen in less than 10 % of the fish at harvest.

The severity of adverse reactions are among different factors dependent upon sanitation, vaccination technique, fish size at vaccination and water temperature during vaccination. As a general precaution it is recommended to perform vaccination at water temperature of 15 °C or below.

Small fish and high water temperature may increase the severity of adverse reactions.

Vaccination may be followed by temporary reduced appetite (2-4 weeks) leading to a transient growth rate reduction (2-4 weeks) not influencing the total weight gain during the life cycle.

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Atlantic salmon (*Salmo salar*) of a minimum weight of 15 g.

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

The recommended dosage is 0.1 ml per fish weighing a minimum of 15 grams.

The vaccine should be left to reach 15-20 °C by keeping it at room temperature over night. The vaccine should be well shaken prior to use. Only administer if the vaccine appears as a homogenous cream coloured emulsion after shaking. Use the entire content within 8 hours after broaching.

The vaccine is intended for administration by intraperitoneal *(i.p.)* injection.

9. ADVICE ON CORRECT ADMINISTRATION

The fish should be anaesthetised prior to injection. Inject 0.1 ml intraperitoneally per fish. The entire needle should be inserted into the midline about one, to one and a half pelvic fin lengths anterior to the base of the pelvic fin. Avoid the introduction of contamination during use.

To reduce the risk of side effects, it is important to deposit the entire dose in the abdominal cavity. The injection needle used should be 0.7 mm diameter (G22) or 0.6 mm diameter (G23) and have appropriate length to penetrate the abdominal wall by 1-2 mm.

The vaccination equipment should be sanitised before use.

Do not administer this product to fish, which have already received this vaccine. Fish with clinical symptoms of disease should not be vaccinated.

Do not vaccinate at water temperatures below 3 °C and above 18 °C. Temperatures close to 18 °C are suboptimal for Atlantic salmon, thus vaccination should preferably be performed at water temperatures of 15 °C or below. Avoid vaccination during smoltification.

An immunisation period of at least 450 degree days from vaccination to transfer to seawater is recommended.

No information is available on the compatibility of this vaccine with any other. Therefore the safety and efficacy of this product when used with any other (either when used on the same day or at different times) has not been demonstrated.

The vaccine should not be used for fish intended as future breeders, as the potential effect of vaccination on the spawning function has not been investigated.

10. WITHDRAWAL PERIOD

Zero degree days

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight of children.
Store and transport refrigerated (2 °C – 8 °C).
Do not freeze.
Protect from light.
Do not use after the expiry date stated on the label.
Shelf life after first opening the container: 8 hours

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

12. SPECIAL WARNING(S)

Ensure that the method of restraint, handling and administration e.g. by the use of guarded needles (such as a protecting device attached to the syringe providing a shield against the tip of the needle), minimises 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 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.

Following injection of an overdose, there is an increased risk of adverse reactions in the form of visceral adhesions and pigmentation, increased risk of mortality and reduced growth.

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 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

August 2012

15. OTHER INFORMATION

15.1 Pharmacotherapeutic group: Aeromonas vaccine and Vibrio vaccine, ATCvet code: QI10AB02
In trials performed with vaccines containing the same and additional antigens and excipients as ALPHA JECT 3000 protection has been demonstrated for up to 12 months. Results from laboratory studies demonstrate RPS_{60} values above 90% for the three antigens in Alpha Ject 3000.

15.2 UVO injection bags made of a multilayer plastic foil with ethylene vinyl acetate as the product contact layer. The giving port is closed with a bromobutyl based rubber stopper.
Pack size: 500 ml

15.3 Method of sale and supply

POM Prescription Only Medicine

15.4 VPA number

VPA number 10804/1/1

For any information about this veterinary medicinal product, please contact:

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