1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ALPHA JECT 3000, emulsion for injection for Atlantic salmon

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 0.1 ml dose contains:

Active substances:
Formaldehyde inactivated bacteria cultures of:
Aeromonas salmonicida subsp. *salmonicida;* AL 2017 RPS[1] $\geq$ 70
Listonella anguillarum serotype O1; AL 112 RPS[2] $\geq$ 75
Listonella anguillarum serotype O2a; AL 104 RPS[2] $\geq$ 75

RPS: Relative Percentage Survival is based on results from challenge studies on Atlantic salmon at end[1] or 60%[2] mortality in the control group.

Adjuvant:
Paraffin, light liquid (mineral oil): 46 mg

Excipients:

Qualitative composition of excipients and other constituents
Polysorbate 80
Sorbitan oleate
Water for injections

White to cream coloured homogeneous emulsion when shaken.

3. CLINICAL INFORMATION

3.1 Target species

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

3.2 Indications for use for each target species

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

Onset of immunity: 450 degree days post vaccination.
Duration of immunity: has not been established.
In trials performed with vaccines containing the same and additional antigens and excipients as this veterinary medicinal product, protection has been demonstrated for up to 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:
Do not administer this veterinary medicinal product to fish which have already received this vaccine.
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.

The severity of adverse events is 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.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
In case of accidental self-administration, seek medical advice immediately and show the package leaflet or the label to the physician. 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 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), melanin accumulation[1].
Common (1 to 10 animals / 100 animals treated):	Adhesion (Speilberg score 3).
Undetermined frequency (cannot be estimated from the available data)	Decreased appetite[2], reduced growth rate[3].

[1] Pigmentation on the viscera occurs frequently, whereas pigmentation in the muscle rarely occurs.
[2] For 2-4 weeks.
[3] For 2-4 weeks, as a result of reduced appetite. Does not influence the total weight gain during the life cycle.

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

Fertility:
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.

3.8 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.

3.9 Administration routes and dosage

Intraperitoneal (i.p.) use.

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

The fish should be anaesthetised prior to injection. Do not vaccinate at water temperatures below 3°C. The vaccination equipment should be sanitised before use.

The vaccine should be left to reach 15-20°C by keeping it at room temperature overnight. The vaccine should not be used if there are signs of a brownish water phase in the bottom of the container. Contact the distributor for further advice. The vaccine should be shaken well prior to use. Only administer if the vaccine appears as a homogenous, cream coloured emulsion.

To reduce the risk of adverse events, 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 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.

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

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.

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: QI10AB02

To stimulate active immunity against *Aeromonas salmonicida*, *Listonella anguillarum* serotype O1 and *Listonella anguillarum* serotype O2a.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 18 months
Shelf life after first opening the immediate packaging: 8 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

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

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)

VPA10804/001/001

8. DATE OF FIRST AUTHORISATION

01/10/2002

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

17/04/2025

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).