SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ALPHA JECT micro 6 emulsion for injection for Atlantic salmon

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 dose (0.05 ml) contains:

Active substances:
Aeromonas salmonicida, strain AL 2017, inactivated ≥ 12.6 $\log_2$ ELISA units
Vibrio anguillarum serotype O1, strain AL 112, inactivated RPS ≥ 75 %
Vibrio anguillarum serotype O2a, strain AL 104, inactivated RPS ≥ 75 %
Aliivibrio salmonicida, strain AL 1134, inactivated RPS ≥ 90 %
Moritella viscosa, strain AL 266, inactivated ≥ 10.7 $\log_2$ ELISA units
Infectious pancreatic necrosis virus serotype Sp., strain AL V103, inactivated 0.12-0.28 AU

ELISA units: Serological response in Atlantic salmon,
RPS: Relative Percentage Survival is based on results from challenge studies on Atlantic salmon at 60% mortality in the control group.
AU: Antigenicity Units (quantity of virus antigen measured in the final product).

Adjuvants:
Paraffin, light liquid (mineral oil): 23 mg.

Excipients:

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

White to cream coloured emulsion.

3. CLINICAL INFORMATION

3.1 Target species

Atlantic salmon of a minimum weight of 25 g.

3.2 Indications for use for each target species

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

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

Duration of immunity:12 months for the bacterial antigens and 5.5 months for IPNV.

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:
Vaccination should preferably be performed at water temperatures of 15°C or below.
Do not vaccinate at water temperatures below 3°C or above 18°C.
Avoid vaccination during smoltification.

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.
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 increase the risk of anaphylactic shock.

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)
Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Adhesion (Speilberg score ≥ 4)

[1] In the abdominal cavity

The severity of adverse reactions may be influenced by different factors such as sanitation, vaccination technique, fish size at vaccination and water temperature during vaccination and in the first 6-12 weeks after 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.

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 potential effect of vaccination on spawning function has not been investigated. Vaccination of broodfish should only be done according to a benefit-risk assessment by the responsible veterinarian/fish health biologist.

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

Posology
Administer a single dose of 0.05 ml per fish. Fish should not be vaccinated more than once.

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. 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.

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

Let the vaccine slowly reach 15-20°C by keeping it at room temperature. Ensure a homogenous emulsion prior to use by squeezing and shaking the vaccine bag for approx. 2 minutes.

Only administer the vaccine if it appears as a homogenous, white to cream coloured emulsion.
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.

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

Following administration of 0.1 ml of the vaccine (double dose) no other adverse reactions than those described in section 3.6 were seen.

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: QI10AL02

Stimulates development of active immunity against *Aeromonas salmonicida, Listonella anguillarum* serotype O1, *Listonella anguillarum* serotype O2a, *Vibrio*

salmonicida, Moritella viscosa and infectious pancreatic necrosis virus (IPNV) in Atlantic salmon.

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: 10 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

Bags made of multilayer plastic foil. The giving port is closed with a sealed rubber stopper. The bag is packed in a zip-lock bag or cardboard box.

Pack sizes:
Zip-lock bag: 250 ml and 500 ml
Cardboard box: 10 x 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 NUMBERS

Vm 21714/5001
Vm 21714/3001

8. DATE OF FIRST AUTHORISATION

15 March 2019

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

July 2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

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

Gavin Hall
Approved 28 August 2025