Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

ALPHA JECT 3000 Emulsion for injection for Atlantic salmon

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance(s):
1 dose (0.1 ml) contains:
Active substances:
Formaldehyde inactivated bacteria cultures of:
Aeromonas salmonicida
subsp. *salmonicida;* AL 2017 RPS[1] ≥ 70
Listonella anguillarum serotype O1; AL 112 RPS[2] ≥ 75
Listonella anguillarum serotype O2a; AL 104 RPS[2] ≥ 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
For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Emulsion for injection.
White to cream coloured homogeneous emulsion when shaken.

4 CLINICAL PARTICULARS

4.1 Target Species

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

4.2 Indications for use, specifying the target species

Reduction of mortality by the diseases caused by *Aeromonas salmonicida* (furunculosis) and *Listonellaanguillarum s*erotype O1 and O2a (vibriosis) in Atlantic salmon.
Onset of immunity occurs :450 degree days post vaccination.

4.3 Contraindications

None.

4.4 Special warnings for each target species

Vaccinate healthy animals only.

4.5 Special precautions for use

Special precautions for use in animals

Do not administer this 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 reactions 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-injection, seek medical advice immediately and show the package leaflet orthe 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 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.

4.6 Adverse reactions (frequency and seriousness)

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, whereas 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.

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.

4.7 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.

4.8 Interaction with other medicinal products and other forms of interactions

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.

4.9 Amounts to be administered and administration route

The recommended dosage is 0.1 ml per fish weighing a minimum of 15 grams. The vaccine is intended for administration by intraperitoneal *(i.p.)* injection. The fish should be anaesthetised prior to injection. Do not vaccinate at water temperature below 3 °C. The vaccination equipment should be sanitized before use.
The vaccine should be left to reach 15 – 20 °C by keeping it at room temperature over night. 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 vaccine should be well shaken prior to use. Only administer if the vaccine appears as a homogenous, cream coloured emulsion. To reduce the risk of adverse effects, it is important to deposit the entire dose in the abdominal cavity. The injection needle used should be 0.7mm 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.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

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.

4.11 Withdrawal period(s)

Zero degree days.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Aeromonas vaccine and Vibrio vaccine,
ATCvet code: QI10AB02
To stimulate active immunity against *Aeromonas salmonicida,Listonella anguillarum* serotype O1 and *Listonella anguillarum* serotype O2a.
No data are available for ALPHA JECT 3000 regarding the duration of immunity
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.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Paraffin, light liquid (mineral oil)
Polysorbate 80
Sorbitan oleate
Water for injection

6.2 Major incompatibilities

Do not mix with any other veterinary medicinal product.

6.3 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.

6.4 Special precautions for storage

Store and transport refrigerated (2°C – 8°C).
Do not freeze.
Protect from light.

6.5 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

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

PHARMAQ AS
Skogmo Industriområde
Industrivegen 50
7863 Overhalla
Norway

8 MARKETING AUTHORISATION NUMBER(S)

VPA10804/001/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 19 December 2008
Date of last renewal: 24 August 2012

10 DATE OF REVISION OF THE TEXT

January 2022