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] ≥ 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:

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)

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: {DD/MM/YYYY}

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

{MM/YYYY}

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).

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Zip-lock bag

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ALPHA JECT 3000 emulsion for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each 0.1 ml dose contains:
Inactivated cultures of:

Aeromonas salmonicida subsp. *salmonicida,* AL 2017	RPS $\geq$ 70
Listonella anguillarum serotype O1, AL 112	RPS $\geq$ 75
Listonella anguillarum serotype O2a, AL 104	RPS $\geq$ 75

3. PACKAGE SIZE

500 ml

4. TARGET SPECIES

Atlantic salmon

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Intraperitoneal use.

7. WITHDRAWAL PERIODS

Withdrawal period: Zero degree days

8. EXPIRY DATE

Exp. {dd/mm/yyyy}

Once broached use within 8 hours.

9. SPECIAL STORAGE PRECAUTIONS

Store and transport refrigerated.
Do not freeze.

Protect from light.

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

11. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

12. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

14. MARKETING AUTHORISATION NUMBERS

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Bag of 500 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ALPHA JECT 3000 emulsion for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each 0.1 ml dose contains:
Inactivated cultures of:

Aeromonas salmonicida subsp. *salmonicida*, AL 2017	RPS $\geq$ 70
Listonella anguillarum serotype O1, AL 112	RPS $\geq$ 75
Listonella anguillarum serotype O2a, AL 104	RPS $\geq$ 75

3. TARGET SPECIES

Atlantic salmon

4. ROUTES OF ADMINISTRATION

Intraperitoneal use.
Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal period: Zero degree days

6. EXPIRY DATE

Exp. {dd.mm/yyyy}

Once broached use within 8 hours.

7. SPECIAL STORAGE PRECAUTIONS

Store and transport refrigerated.
Do not freeze. Protect from light.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

9. BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

ALPHA JECT 3000 emulsion for injection for Atlantic salmon

2. 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): 46mg

White to cream coloured homogeneous emulsion when shaken.

3. Target species

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

4. Indications for use

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 after 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.

5. Contraindications

None.

6. Special warnings

Special warnings:
Vaccinate healthy animals only.

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-injection, 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.

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.

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:
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.

Major incompatibilities:
Do not mix with any other veterinary medicinal product.

7. 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 product. 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 contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system: {national system details}

8. Dosage for each species, routes and method of administration

Intraperitoneal (i.p.) use.

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

9. Advice on correct administration

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 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 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.

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

10. Withdrawal periods

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 immediate packaging: 8 hours.

12. Special precautions for disposal

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 applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

[MA number]

Package size:
500 ml

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

MM/YYYY

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release and contact details to report suspected adverse reactions:
PHARMAQ AS
7863 Overhalla
Norway
E-mail: phq.phvig@zoetis.com
Tel: +47 23 29 85 00

<17. Other information>