PARTICULARS TO APPEAR ON THE OUTER PACKAGE {Bag Label}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Alpha Ject 2-2 Emulsion for Injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Active substances:

1 dose (0.1 ml) contains:

Formaldehyde inactivated cultures of:

Aeromonas salmonicida subsp. *Salmonicida*	RPS $\geq$ 80 (Ph. Eur.)
Infectious Pancreatic Necrosis Virus (IPNV) serotype Sp	RP 1.5 – 4.8

Adjuvant:

Liquid paraffin.

3. PHARMACEUTICAL FORM

Emulsion for injection

4. PACKAGE SIZE

500 ml (5000 doses)

5. TARGET SPECIES

Atlantic salmon (Salmo salar L.) of a minimum weight of 39 g

6. INDICATION(S)

Furunculosis and IPNV vaccine

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Intraperitoneal (i.p.) injection

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Zero days

9. SPECIAL WARNING(S), IF NECESSARY

Accidental injection is dangerous. Seek immediate medical advice in case of any self-injection. Show the package leaflet to the medical practitioner.

10. EXPIRY DATE

Once opened, use by 8 hours.

11. SPECIAL STORAGE CONDITIONS

Store and transport refrigerated (2^{o}C – 8^{o}C).

Do not freeze.

Protect from light.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Do not reuse opened containers. Disposal: read package leaflet

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE *[Distribution category]*

POM-VPS

For animal treatment only. To be supplied only on veterinary prescription.

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

KEEP OUT OF THE SIGHT AND REACH OF CHILDREN

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

PHARMAQ AS, Skogmo Industriområde, N-7863 Overhalla, Norway

16. MARKETING AUTHORISATION NUMBER(S)

Vm 21714/4000

17. MANUFACTURER'S BATCH NUMBER

PACKAGE LEAFLET FOR:

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 2-2 emulsion for injection

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

Active substances:

1 dose (0.1 ml) contains:

Formaldehyde inactivated cultures of:

Aeromonas salmonicida subsp. *Salmonicida*	RPS[1] $\geq$ 80 (Ph. Eur.)
Infectious Pancreatic Necrosis Virus (IPNV) serotype Sp	RP[2] 1.5 – 4.8

Adjuvant:

Liquid paraffin.

4. INDICATION(S)

Prevent mortality of the disease caused by furunculosis and reduce mortality of the caused by IPN in Atlantic Salmon.

The onset of immunity occurs no later than 600 degree days from vaccination.

The protection against *Aeromonas salmonicida* lasts for at least 12 months post vaccination. Protection against IPNV has been demonstrated for up to two and a half

[1] The biological activity of one dose is given as RPS (Relative Percentage Survival) specified according to the Ph. Eur. monograph given above and defined by the quotation: [1-(mortality vaccinated fish/mortality mock vaccinated fish)] x 100.

[2] Relative Potency

months in field trials performed with a vaccine containing IPNV and additional antigens to those found in ALPHA JECT 2-2.

5. CONTRAINDICATIONS

Do not use in fish intended for broodstock.

6. ADVERSE REACTIONS

Adverse reactions in the form of visceral adhesions and pigmentation may occur. Adhesions between the abdominal wall and the viscera in addition to pigmentation on the viscera and abdominal wall are normally seen. Vaccinated fish show some growth retardation compared to non-vaccinated fish.

Following injection of an overdose, there is an increased risk of development of more severe lesions in the abdominal cavity, characterised by more severe pigmentation and adhesions between the abdominal wall and viscera.

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 L.) of a minimum weight of 39 g

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

The recommended dosage is 0.1 ml per fish.

The vaccine should be left to slowly reach 15 °C – 20 °C by keeping it at room temperature. Mix the vaccine well prior to use by shaking and squeezing the container for approximately two minutes.

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.

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 diameter, and length to penetrate the abdominal wall by 1 - 2 mm.

The vaccination equipment should be disinfected before use. Administration of the vaccine must be performed using an injection system that prevents back flush of the vaccine into the vaccine tube/container.

10. WITHDRAWAL PERIOD(S)

Zero 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. Shelf-life after first broaching the immediate packaging: 8 hours. Do not re use opened containers.

12. SPECIAL WARNING(S)

Do not administer this product to fish which have already received this vaccine. Fish with clinical signs of disease must not be vaccinated. Do not vaccinate at water temperatures below 1 °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 600 degree-days from vaccination to transfer to seawater is recommended.

Occasional mortality may occur if individuals fail to respond or the immune system is suppressed by concurrent infections, poor nutritional status, genetic factors, smoltification or other stressful environmental conditions.

Only administer if the vaccine appears as a homogenous, white to cream coloured emulsion after shaking. If the vaccine shows signs of a brownish water phase in the bottom of the container, it should not be used for vaccination. Contact the distributor for further advice.

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 other veterinary medicinal product therefore needs to be decided on a case by case basis.

Do not mix with any other veterinary medicinal product.

For Animal Treatment Only

<u>Special precautions to be taken by the person administering the veterinary medicinal product to animals</u>

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 insert 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.

Repeated self-injections may aggravate the effects or cause anaphylactic shock

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

POM – VPS To be supplied only on veterinary prescription

Vm 21714/4000

Pack size: 500ml

Approved: 10/01/2018