SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ALPHA JECT 2-2 emulsion for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Qualitative composition	Quantitative composition
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.	
Excipient:	
For the full list of excipients, see section 6.1	

3. PHARMACEUTICAL FORM

Emulsion for injection.

4. CLINICAL PARTICULARS

4.1 Target species

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

4.2 Indications for use, specifying the target species

For active immunisation of Atlantic salmon to prevent mortality of the disease caused by *Aeromonas salmonicida* (furunculosis) and to reduce mortality of the disease caused by IPNV (infectious pancreatic necrosis).

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

[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

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

4.3 Contraindications

Confer section 4.7.

4.4 Special warnings for each target species

An immunisation period of at least 600 degree-days from vaccination to transfer to seawater is recommended.

4.5 Special precautions for use

i. Special precautions for use in animals

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.

The severity of the undesirable effects is among other things, dependent on hygiene, vaccination technique, size of the fish at vaccination and water temperature during vaccination.

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.

Administration of the vaccine must be performed using an injection system that prevents back flush of the vaccine into the vaccine tube/container.

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.

ii. Special precautions to be taken by the person administering the veterinary medicinal product to animals

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 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.

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

4.6 Adverse reactions (frequency and seriousness)

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.

4.7 Use during pregnancy, lactation or lay

Do not use in fish intended for broodstock.

4.8 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 other veterinary medicinal product therefore needs to

be decided 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 39 g. The vaccine is intended for administration by intraperitoneal *(i.p.)* injection. The fish should be anaesthetised prior to injection. Vaccinate at water temperatures from 1 °C – 18 °C and preferably below 15 °C. The vaccination equipment should be disinfected before use.

The vaccine should be left to slowly reach 15 °C – 20 °C by keeping it at room temperature. The vaccine should be well shaken prior to use.

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 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 development of more severe lesions in the abdominal cavity, characterised by more severe pigmentation and adhesions between the abdominal wall and viscera. Regarding growth retardation please confer section 4.6

4.11 Withdrawal period(s)

Zero days.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Inactivated viral and inactivated bacterial vaccines
ATCvet code: QI10AL.

To stimulate active immunity against *Aeromonas salmonicida* and infectious pancreatic necrosis virus (IPNV).

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Liquid paraffin
Macrogolglycerol hydroxystearate
Sorbitan oleate

6.2 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: 1 year.
Shelf-life after first broaching the immediate packaging: Use within 8 hours and do not re use opened containers.

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. The giving port is closed with a sealed rubber stopper.
Pack size: 500 ml (corresponding to 5000 doses)

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

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

7. MARKETING AUTHORISATION HOLDER

PHARMAQ AS
Skogmo Industriområde
N-7863 Overhalla
Norway

8. MARKETING AUTHORISATION NUMBER

Vm: 21714/4000

9. DATE OF FIRST AUTHORISATION

Date: 11 March 2009

10. DATE OF REVISION OF THE TEXT

Date: February 2014

PROHIBITION OF SALE, SUPPLY AND/OR USE:

Not applicable

 27 February 2014