1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ALPHA JECT 2000 emulsion for injection for sea bass

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose (0.1 ml) contains:
Active substance:
Inactivated *Listonella anguillarum* (*Vibrio anguillarum)* serotype O1, strain AL 112 RPS[1] $\geq$ 75
Inactivated *Photobacterium damselae* subsp. *piscicida*, strain AL 5051 RPS[2] $\geq$ 60

[1] RPS (Relative Percentage Survival) is based on results from challenge studies and calculated according to the following quotation: [1-(% mortality in vaccinated fish/60% mortality in mock vaccinated fish)] x 100.
2 RPS (Relative Percentage Survival) is based on results from challenge studies and calculated according to the following quotation: [1-(% mortality in vaccinated fish/% mortality in mock vaccinated fish)] x 100.

Adjuvant: Liquid paraffin (mineral oil): 46 mg

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

Sea bass (*Dicentrarchus labrax*)

4.2 Indications for use, specifying the target species

For active immunisation of sea bass to reduce mortality and clinical signs caused by *Vibrio anguillarum* serotype O1 (vibriosis) and *Photobacterium damselae* subsp. *piscicida* (pasteurellosis).

Onset of immunity: 4 weeks at 20 ºC (560 degree days) .

Duration of immunity: 3 months at 22 ºC (1.980 degree days)**.**

4.3 Contraindications

None

4.4 Special warnings for the target species

Due to handling stress, vaccination may be followed by temporary reduced appetite.

Vaccinate healthy animals only.

4.5 Special precautions for use

Special precautions for use in animals
The vaccination equipment should be disinfected before use.
Special precautions to be taken by the person administering the veterinary medicinal product to animals

The use of needle guards is recommended in order to reduce the risk of accidental self-injection during manual vaccination.

After vaccination the equipment used for vaccination should be thoroughly cleaned.

People with known hypersensitivity to fish vaccines should avoid contact with the veterinary medicinal product as the consequences of self-injection are not known.

The product should not be administered by pregnant women.

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)

Oil adjuvants are associated with increased risk of adverse reactions in the form of visceral adhesions and pigmentation in the abdomen.

Very common (> 1/10):
- Up to 16 months post vaccination mild adhesions are observed, often close to the injection site.
- Up to 16 months post vaccination small amount of melanin, seen as spots covering very limited areas of the viscera have been observed.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports)

4.7 Use during pregnancy, lactation or lay

The safety of the veterinary medicinal product has not been established for use in broodstock, and vaccination of broodstock should be subject to a risk benefit evaluation of the prescribing veterinarian.

4.8 Interaction with other medicinal products and other forms of interaction

No information is available on the safety and efficacy of 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 dose is 0.1 ml per fish of a minimum weight of 15 grams. The vaccine should be administered by intraperitoneal (IP) injection. The fish should be anaesthetised prior to injection. It is recommended to starve the fish for a minimum of 24 hours before vaccination.

The vaccine should be left to slowly reach 15-20°C by keeping it at room temperature. 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, white to cream coloured emulsion.

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 by 1-2 mm. The entire needle should be inserted into the midline about one, to one and a half pelvic fin length posterior to the base of the pelvic fin.

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

Not known

4.11 Withdrawal period(s)

Zero degree days

5 IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Immunologicals for pisces, others.
ATCvet code: QI10X.

No cross protection between different serotypes has been demonstrated.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Paraffin, light liquid
Sorbitan oleate
Polysorbate 80
Water, purified

The vaccine may contain formaldehyde as a residue after inactivation.

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: 2 years.
Shelf-life after first opening the immediate packaging: 10 hours.

6.4. Special precautions for storage

Store and transported refrigerated (2-8°C).
Do not freeze.
Protect from direct sunlight.

6.5 Nature and composition of immediate packaging

High density polyethylene (HDPE) bottle which is closed with bromo butyl rubber stopper and aluminium cap.

Package size:
500 ml (5000 doses) bottles

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
Industrivegen 50
7863 Overhalla
Norway

8. MARKETING AUTHORISATION NUMBER(S)

MA no.:

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: DD/MM/YYYY

10 DATE OF REVISION OF THE TEXT

DD/MM/YYYY

PROHIBITION OF SALE, SUPPLY AND/OR USE

To be supplied only on veterinary prescription.