PACKAGE LEAFLET FOR:
ALPHA JECT 2000 emulsion for injection for sea bass

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder and manufacturer responsible for batch release:

PHARMAQ AS
Skogmo Industriområde
Industrivegen 50
7863 Overhalla
Norway

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

ALPHA JECT 2000 emulsion for injection for sea bass

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

Each dose (0.1 ml) contains:
Active substance:

Inactivated *Listonella anguillarum (Vibrio anguillarum)* serotype O1, strain AL 112	RPS[1] ≥ 75
Inactivated *Photobacterium damselae* subsp. *piscicida*, strain AL 5051	RPS[2] ≥ 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

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

4. INDICATION

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 (1980 degree days)

5. CONTRAINDICATIONS

None.

6. ADVERSE REACTIONS

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)

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 inform your veterinary surgeon.

7. TARGET SPECIES

Sea bass (*Dicentrarchus labrax*)

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

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.

9. ADVICE ON CORRECT ADMINISTRATION

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.

10. WITHDRAWAL PERIOD(S)

Zero degree days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

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

Do not use this veterinary medicinal product after the expiry date which is stated on the label.

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

Do not use if the vaccine shows signs of a brownish water phase in the bottom of the container before shaking. Contact the manufacturer for further advice.

12. SPECIAL WARNINGS

Special warnings for each target species:
Due to handling, vaccination may be followed by temporary reduced appetite.

Vaccinate healthy animals only.

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.

Pregnancy/Lactation/Lay/Fertility:
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.

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 (symptoms, emergency procedures, antidotes):
Not known.

Incompatibilities:
Do not mix with any other veterinary medicinal product.

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

Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

DD/MM/YYYY

15. OTHER INFORMATION

Package size:
500 ml bottles

No cross protection between different serotypes has been demonstrated.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder: