Alpha Ject 2000
Package leaflet

Vibriosis and Pasteurellosis Vaccine

1. NAME OF THE IMMUNOLOGICAL VETERINARY MEDICINAL PRODUCT

ALPHA JECT 2000, emulsion for injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES (COMPOSITION)

One dose (0.1 ml) of vaccine contains;

Formalin inactivated bacteria cultures containing;

Listonella anguillarum (serotype O1)	RPS[1)] $\geq$ 75
Photobacterium damselae subsp. *piscicida*	RPS[1)] $\geq$ 60

Adjuvant: Liquid paraffin

3. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Producing Company
PHARMAQ AS
Industrivegen 50
N-7863 Overhalla
NORWAY

Importer Company
PHARMAQ Veteriner Ecza Deposu ve Su Ürünleri Tic Ltd. Şti
KARACAOGLAN MAH. 6166 SK. 21 A BORNOVA
Izmir 35070, Türkiye
Tel: 0090 232 422 2310
Fax: 0090 232 422 3227

4. TARGET SPECIES

Sea bass

5. INDICATION

Prevent mortality and clinical signs caused by the diseases vibriosis and pasteurellosis.

[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.

6. DOSAGE FOR EACH SPECIES

0.1 ml per fish.

7. METHOD AND ROUTE OF ADMINISTRATION

The following vaccination scheme is recommended:
The vaccination will be performed by injection (ALPHA JECT™ 2000) of fish with a minimum weight of 15 grams.

Vaccination by Injection:
The recommended dosage is 0.1 ml per fish by intraperitoneal (i.p) injection.
Food should be withheld for at least 24 hours and the fish should be anaesthetized prior to injection.
It is important to deposit the entire dose in the abdominal cavity. The entire needle should be inserted into the midline about one or one and a half pelvic fin lengths posterior to the base of the pelvic fin.
Use a stainless steel needle of approximately 0.6 mm in diameter. Select the appropriate needle length by inserting it deep enough to fully penetrate the abdominal wall at the injection site (1-2 mm).

8. ADVICE ON CORRECT ADMINISTRATION

To reduce stress and to prevent scale and skin damage during handling, crowd the fish into a tarpaulin enclosure and gradually anaesthetize the fish so that the fish appear calm but not immobilized. The fish are netted up from the tarpaulin enclosure using a wide bottom and knotless dip-net, and immediately immersed into an aerated solution containing anesthesia. After one to two minutes of exposure, the fish become fully anaesthetized (immobilized). Fully anaesthetized fish are netted onto a vaccination table.
Do not transfer more fish into the anesthesia or onto the vaccination table before the treated fish wake up.
The water temperature on the vaccination table shall not vary more than 2 ºC from the temperature of the rearing water. Aerate and replace the anesthetic solution and the water on the vaccination table when needed.
Once each fish is vaccinated, place it immediately into clean rearing water.
Start vaccination using cleaned and disinfected vaccination table and vaccination equipment. Clean and disinfect vaccination table and equipment at the end of each working day.

Shake the vaccine bottle well prior to use. A sterile plastic hose containing a 0.2 micrometer (µm) filter and a capped vaccine connecting needle comes provided with the product. Remove the seal from the vaccine bottle and the cap from the connecting needle. Without allowing the exposed connecting needle to touch any other surface, pass it through the rubber stopper of the vaccine bottle. Hang the vaccine bottle converted over the vaccination table and connect the other end of the plastic hose to the injection device. To allow for air displacement in the vaccine bottle during use, open the small lid of the plastic hose covering the microfilter. Pump the vaccine through the plastic hose using the injection device and calibrate so that 0.1 ml is delivered in each dose. When vaccinating during cold air temperatures, temperate the vaccine to 15 – 20 °C prior to use and during use by keeping the vaccine bottle and the plastic hose underneath protective clothing.

If using an automatic vaccination machine, follow the manufacturer's instructions carefully. For manual vaccination using hand-held vaccination guns, lift the fish carefully with the abdomen up and the head pointing away from you, so that is weight is evenly distributed in the hand. Do not put any side pressure on the fish.

Fish scales may compile on the needle during vaccination. Assure to remove the needle from fish scales regularly. The needle should be changed whenever sharpness is notably reduced.

When conducting injection vaccination at sea cage site, there are two options. One is to vaccinate the fish from one cage and transfer them into another empty cage or to separate cages when assorting fish-size is being performed during the vaccination process. The other option is to split the sea cage into two compartments with help of the floating line and transferring the vaccinated fish from one compartment to the other.

9. DURATION OF PROTECTION

Documented for at least 5 months**.**

10. CONTRAINDICATIONS

None

11. UNDESIRABLE EFFECTS

Due to handling stress, vaccination may be followed by temporary reduced appetite. If you notice any other side effects, please inform your veterinary surgeon.

12. LEGAL WITHDRAWAL PERIOD

Zero days.

13. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight of children.
Store in the dark at 2-8 °C. Do not freeze. Protect from sunlight.
Use the entire content when first opened within the same working day.
Do not use after the expiry date stated on the label.

The vaccine should appear as a homogenous, cream coloured emulsion after shaking. Do not use ALPHA JECT 2000 if you notice that the vaccine shows sign of a brownish water phase in the bottom of the container. Contact the distributor for further advice.

14. SPECIAL WARNINGS

Do not administer this product to fish, which have already received this vaccine. Fish with clinical symptoms of disease should not be vaccinated.

In any population there will be a small number of individuals, which fail to respond fully to vaccination. Occasional mortality may occur if individuals fail to respond or the immune system is suppressed by concurrent infections, poor nutritional status, genetic factors or other stressful environmental conditions.

To the user:

This product is an oil-based compound. Accidental injection/self injection may result in severe pain and swelling and could result in the loss of the affected finger or thumb if prompt medical attention is not given. Method of restraint, the use of guarded needles may minimise the risk of accidental self-injection during handling and administration.
If you are accidentally injected with this product, go AT ONCE to the nearest accident and emergency (casualty) department of a hospital and show the information printed below to the doctor (or nurse) on duty. Seek prompt medical advice even if only a very small amount is injected.
If pain persists for more than 12 hours after medical examination, seek further medical advice. Should not be administrated by pregnant women

To the doctor:
Even if very tiny amounts have been injected, accidental injection with this oil-based product can cause intense swelling which may, for example, result in ischemic necrosis and 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.

15. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS DERIVED FROM SUCH VETERINARY MEDICINAL PRODUCTS

Any unused veterinary medicinal product or waste material derived from such veterinary medicinal product should be disposed by applying disinfectant or by incineration.

16. DATE ON WHICH THE PACKAGE INSERT WAS LAST REVISED

April 2015

17. OTHER INFORMATION

For every kind of information about this veterinary medicinal product, please contact the local representatives of the authorisation holder firm.

PACKAGE TYPE: 500 ml

DATE AND NUMBER OF MARKETING LICENCE: 01.02.2013 – PY0008

FOR VETERINARY USE ONLY.