

PACKAGE LEAFLET

Autogenous *Aeromonas veronii* vaccine emulsion for injection
Target species: Sea bass (*Dicentrarchus labrax*)

1 NAME AND ADDRESS OF THE MANUFACTURER

PHARMAQ AS
Skogmo Industriområde
N-7863 Overhalla, NORWAY

Distributor:
AQUA VET SA
48, Antiochias street
14341 Athens, GREECE

2 NAME OF THE IMMUNOLOGICAL VETERINARY MEDICINAL PRODUCT

Autogenous *Aeromonas veronii* vaccine emulsion for injection

3 STATEMENT OF THE ACTIVE AND OTHER SUBSTANCES

One dose (0.05 ml) vaccine contains:

Formaldehyde inactivated bacterial culture of: *Aeromonas veronii*

Adjuvant: Mineral oil (Paraffin light liquid)

4 INDICATION

Reduce mortality and clinical signs caused by *Aeromonas veronii*

5 CONTRAINDICATIONS

None

6 UNDESIRABLE EFFECTS

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

7 TARGET SPECIES

Sea bass (*Dicentrarchus labrax*)

8 DOSAGE, METHOD AND ROUTE OF ADMINISTRATION

Recommended dose is 0.05 ml per fish of a minimum weight of 15 grams. It is recommended to starve the fish for 24 hours prior to vaccination.

The vaccine should be left to slowly reach 15-20°C. Mix the vaccine well by shaking and squeezing the container for approximately 2 minutes. After shaking, the vaccine should be a homogenous white to cream coloured suspension.

The vaccine is administered by intraperitoneal (i.p.) injection.

9 ADVICE ON CORRECT ADMINISTRATION

To reduce stress and to prevent skin damage during handling, the fish must be anaesthetized prior to injection. Dose: 0.05 ml i.p. per fish. It is important to deposit the entire dose in the abdominal cavity. The entire needle should be inserted into the midline about one pelvic fin length posterior to the base of the pelvic fin. Use a stainless steel needle of approximately 0.6 mm in diameter. Select an appropriate needle length to fully penetrate the abdominal wall at the injection site by 1-2 mm.

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.



The water temperature on the vaccination table should not differ with more than 2°C from the temperature of the rearing water. Once each fish is vaccinated, place it immediately into clean rearing water.

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

10 WITHDRAWAL PERIOD

Not applicable (Zero days)

11 SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight of children.

Store and transport at 2-8°C. Do not freeze. Protect from sunlight.

Once opened, use the entire content within 12 hours.

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 the vaccine 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.

12 SPECIAL WARNINGS

In any population there may 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 operator: This product contains mineral oil. Accidental injection/self injection may result in severe pain and swelling and could result in the loss of the affected finger if prompt medical attention is not given. Ensure that the method of handling and administration, e.g. by the use of guarded needles, minimises the risk of accidental self-injection. 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 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 ischaemic 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.

13 SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS

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

14 DATE ON WHICH THE PACKAGE LEAFLET WAS LAST REVISED

October 2012

15 OTHER INFORMATION

For further information on this veterinary medicinal product, please contact the local representative of PHARMAQ AS:

AQUA VET SA
48, Antiochias Street
14341 Athens, Greece

Tel: 210 2517807

Fax: 210 2581981

