
ENGLISH TRANSLATION - PROPOSED VACCINE PACKAGE INSERT**Vibriosis and pasteurellosis vaccine****1 NAME OF THE IMMUNOLOGICAL VETERINARY MEDICINAL PRODUCT**

ALPHA DIP™ 2000, dip suspension
Sea bass

2 STATEMENT OF THE ACTIVE AND OTHER SUBSTANCES

Formalin inactivated bacteria cultures of *Listonella anguillarum* (serotype O1) and *Photobacterium damsela* subsp. *Piscicida*.

3 NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

PHARMAQ AS
Skogmo Industriområde
N-7863 Overhalla
NORWAY

Distributor:
AQUA VET SA
48, Antiochias street
143 41 Athens, GREECE

4 TARGET SPECIES

Sea bass

5 INDICATION

Prevent mortality and clinical signs caused by *Listonella anguillarum* serotype O1 (vibriosis) and *Photobacterium damsela* subsp. *piscicida* (pasteurellosis). The product is intended for primary and re-vaccination.

6 DOSAGE FOR EACH SPECIES

Dipping of the fish into the diluted vaccine for 30 seconds

7 METHOD AND ROUTE OF ADMINISTRATION

The following vaccination scheme is recommended:

First and second vaccination by dipping (ALPHA DIP 2000) of fish with average weight approx. 1 gram and 5 grams respectively. The third vaccination will be performed by injection (ALPHA JECT 2000) of fish with a minimum weight of 15 grams.

Primary vaccination is intended for fish residing in the hatchery that average 1 g in weight. Vaccinate minimum 2 weeks prior to transfer to sea cages. Temperate the vaccine and shake the vaccine bottle prior to use. Dilute one litre of vaccine with 9 litres of clean rearing water (1:10 dilution). Immerse the fish into the diluted vaccine for 30 seconds. Discard the vaccine when a total of 20 kg fish have been immersed per 10 litre of the diluted vaccine.

Revaccination is intended for fish residing in sea cages that average 5 g in weight. Temperate the vaccine and shake the vaccine bottle prior to use.

Dilute one litre of vaccine with 9 litres of clean rearing water (1:10 dilution). Immerse the fish into the diluted vaccine for 30 seconds. Discard the vaccine when a total of 100 kg fish have been immersed per 10 litre of the diluted vaccine.

8 ADVICE ON CORRECT ADMINISTRATION

Vaccinate only fish free of clinical symptoms of disease, demonstrating normal behavior. For fish safety, avoid vaccinating at water temperature higher than 25°C and during periods with rapidly increasing or decreasing water temperatures.

Shake well the vaccine bottle prior to use.

9 CONTRAINDICATIONS

None

10 UNDESIRABLE EFFECTS

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

11 WITHDRAWAL PERIOD

Zero days.

12 SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight of children.

Store in 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.

13 SPECIAL WARNINGS

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.

14 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 products should be disposed of in accordance with local requirements.

15 DATE ON WHICH THE PACKAGE INSERT WAS LAST REVISED

September 2012

16 OTHER INFORMATION

For any information about this veterinary medicinal product, please contact the local representative of the Marketing Authorization Holder.

Aqua- Vet S.A.
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