#### **ENGLISH TRANSLATION**

Only For Use in Animal Health.

#### 1 NAME OF THE BIOLOGICAL VETERINARY MEDICINAL PRODUCT

ALPHA DIP 2000 ,Formalin inactivated dip suspension against Vibriosis and Pasteurellosis in seabass

#### 2 PHARMACEUTICAL FORM

Dip suspension

# 3 STATEMENT AND POWER OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Formalin inactivated bacteria cultures of:

Listonella anguillarum (serotype O1) RPS ≥ 75 Photobacterium damselae subsp. piscicida RPS ≥ 60

#### 4 INDICATIONS

Prevents Clinical symptoms and mortality caused by Listonella anguillarum serotype O1 (Vibriosis) and Photobacterium damselae subsp. piscicida (pasteurellosis). The product is intended for the first and second vaccination.

#### 5 CONTRAINDICATIONS

None

## 6 ADVERSE EFFECTS

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

### 7 TARGET SPECIES

Sea bass

#### 8 DOSAGE FOR EACH SPECIES

Dilute one litre of vaccine with 9 litres of clean rearing water. Immerse the fish into the diluted vaccine suspension for 30 seconds in the knotless net. Feeding should be withheld at least one day before the vaccination. Temperate the vaccine to the room temperature and shake the vaccine bottle prior to use.

## 9 METHOD AND ROUTE OF ADMINISTRATION

The following vaccination scheme is recommended:

First and second vaccination is applied by by dipping (ALPHA DIP 2000) of fish with average weight approxemately 1 gram and 5 grams respectively.

<u>Primary vaccination</u> 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 to room temperature 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.

<u>Second Vaccination</u> 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.

#### 10 LEGAL WITHDRAWAL PERIOD

Zero days

#### 11 COMMERCIAL PACKAGING INFORMATION:

1000 MI, White HDPE bottles, in carton boxes of 10 units

#### 12 SPECIAL STORAGE PRECAUTIONS AND SHELF LIFE

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. Shelf life is 24 months.

#### 13 SPECIAL PRECAUTIONS

In any population there will be a small number of individuals, which fail to respond well 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 ADVICE ON CORRECT ADMINISTRATION FOR VACCINATORS AND VETERINARIES

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.

# 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 products should be disposed with help of disinfectants or by burning.

#### 16 WARNINGS

Keep out of the reach and sight of children.

Consult to a veterinarian if an unexpected effect is observed.

Please refer to the packaging insert for detailed information about the

Please refer to the packaging insert for detailed information about the use of the vaccine before use

#### 17 NAME AND ADDRESS OF THE LICENCE HOLDER

Manufacturer PHARMAQ AS Industrivegen 50 N-7863 Overhalla NORWAY

Importer company

PHARMAQ Veteriner Ecza Deposu ve Su Ürünleri Ticaret Limited Şirketi.

Address: KARACAOĞLAN MAH.6166 SK. 21/A BORNOVA

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#### 18 MARKETING AUTHORISATION DATE AND NUMBER

11.05.2015 / P-0076

#### 19 DATE ON WHICH THE PACKAGE INSERT WAS LAST REVISED

July 2015

#### **20 OTHER INFORMATION**

For any further information about this veterinary medicinal product, please contact your local license holder company officials.