VACCINE PACKAGE INSERT

*Edwardsiella ictaluri* vaccine

1. **NAME OF THE IMMUNOLOGICAL VETERINARY MEDICINAL PRODUCT**
   ALPHA JECT® Panga 1 emulsion for injection

2. **TARGET SPECIES**
   *Pangasianodon hypophthalmus*

3. **COMPOSITION**
   Formalin inactivated bacteria cultures containing:
   *Edwardsiella ictaluri*
   Adjuvant and emulsifiers

4. **INDICATION**
   Prevent the clinical signs of septicaemia in *Pangasianodon hypophthalmus* caused by *Edwardsiella ictaluri*.

5. **DOSAGE AND ADMINISTRATION**
   The recommended dose of ALPHA JECT® Panga 1 is 0.05 ml per fish.
   The vaccination will be performed by injection of fish weighing not less than 10g.

   Vaccination by injection:
   The entire needle should be inserted into the midline, at ½ - ¾ the length of the pelvic, anterior to the base of the pelvic fin. It is important to deposit the entire dose in the abdominal cavity.
   Feed should be withheld for at least 48 hours and the fish should be anaesthetised prior to injection.

   The population of fish should be of uniform size. Prior to vaccination, the thickness of the body wall at the site of injection should be evaluated by opening the peritoneal cavity and visually inspecting the penetration of the vaccination needle through the abdominal wall. The needle should penetrate the abdominal wall by 1.5 mm. Use a stainless steel needle with a diameter of approximately 0.6 mm and needle length in accordance with the abdominal wall thickness.

   The vaccine should be left to reach 15-20°C and well shaken 2 – 5 minutes prior to use.

6. **ADVICE ON CORRECT ADMINISTRATION**
   Do not transfer more fish into the anaesthesia or onto the vaccination table at a time than can be vaccinated before onset of recovery. The water temperature on the vaccination table shall not vary more than 2 °C from the temperature of the rearing water. Aerate and replace the anaesthetic 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 the exposed connecting needle allowed to touch any other surface, insert immediately 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 0.05 ml is delivered in each dose. In order to keep the vaccine tempered during vaccination, cover the bottle with a wet towel, and keep the towel moist during vaccination.

For manual vaccination using hand-held vaccination guns, other hand lifts the fish carefully with the abdomen up. Do not put any side pressure on the fish.

The needle should be changed whenever sharpness is notably reduced.

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

8 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.

9 SPECIAL PRECAUTIONS
No withdrawal period is required before slaughter.
Keep out of the reach and sight of children.
Pregnant women should not attend vaccination
Store in the dark at 2-8 °C. Do not freeze. Protect from sunlight.
Use the entire content when first opened within 24 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 ALPHA JECT® Panga 1 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.

10 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.

To the user: ALPHA JECT® Panga 1 is an oil-based vaccine. 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. Ensure
that the method of restraint, 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, 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.**

**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.

**11 INSTRUCTION FOR THE DISPOSAL OF UNUSED PRODUCTS**

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

**12 PACKING**

Real volume of vaccine 500 ml

**13 MANUFACTURED BY**

PHARMAQ AS
Skogmo Industriområde
N-7863 Overhalla, NORWAY

**14 DISTRIBUTED BY**

MINH TAN COMPANY LIMITED

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