VACCINE PACKAGE INSERT

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

ALPHA JECT® Panga 2

2 TARGET SPECIES

Pangasianodon hypophthalmus

3 COMPOSITION

Formalin inactivated bacteria cultures of:

Aeromonas hydrophila serotype A (AL 20 136)
Aeromonas hydrophila serotype B (AL 20 212)
Edwardsiella ictaluri (AL 20 658)

Adjuvant and emulsifiers

4 INDICATION

For active immunization to prevent and reduce mortality and clinical signs of MAS (Motile Aeromonad Septicaemia) caused by *Aeromonas hydrophila* and enteric septicemia and white spot on liver, kidney and spleen caused by *Edwardsiella ictaluri* in *Pangasianodon hypophthalmus.*

Onset of immunity against disease caused by *Aeromonas hydrophila* and *Edwardsiella ictaluri* demonstrated from one and three weeks after vaccination, respectively.

Duration of immunity against disease caused by *Aeromonas hydrophila* and *Edwardsiella ictaluri* demonstrated for at least 30 and 22 weeks after vaccination, respectively.

5 DOSAGE AND ADMINISTRATION ROUTE

Inject 0.05 ml intraperitoneally in fish of minimum 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.

The population of fish should be of uniform size. Prior to vaccination, the thickness of the abdominal 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.

Feed should be withheld for at least 48 hours and the fish should be anaesthetized prior to injection.

The vaccine should be well shaken for minimum 2 minutes prior to use.

6 ADVICE ON CORRECT ADMINISTRATION

Do not transfer more fish into the anesthesia 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 2ºC 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 bag well prior to use. A sterile plastic hose containing a connecting needle is provided with the vaccine bag. Remove the seal from the vaccine bag and the sterile plastic hose. Immediately, insert the connecting needle through the rubber stopper of the vaccine bag without exposing it to any other surface. Hang the vaccine bag converted over the vaccination table and connect the other end of the plastic hose to the injection device. In order to keep the vaccine tempered during vaccination, cover the vaccine bag with a moist fabric, and keep the towel moist during vaccination. Keep vaccine bag out off direct sunlight during vaccination.
Pump the vaccine through the plastic hose using the injection device and calibrate so that 0.05 ml is delivered in each dose.

When vaccinating, lift the fish carefully with the abdomen facing upwards. 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. Reduced efficacy may be observed if the immune system is suppressed by e.g. concurrent infections, poor nutritional status, or stressful environmental conditions.

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

Don’t need to stop applying product before slaughter.
Keep out of the reach and sight of children.
Pregnant women should be extra careful if performing vaccination.
Store and transport at 2-8 °C.
Do not freeze.

Protect from sunlight.
When first opened, use the entire content within 10 hours.
Do not use after the expiry date stated on the label.

Do not use ALPHA JECT® Panga 2 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

To the user:
ALPHA JECT® Panga 2 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 small 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 vaccine or waste materials should be disposed of in accordance with the local requirements.

12 PACKAGING

Real volume of vaccine 250 ml or 500 ml.
Not all pack sizes may be marketed.

13 MANUFACTURED BY

PHARMAQ AS
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N-7863 Overhalla, Norway

14 IMPORTED BY

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ONLY USE FOR VETERINARY PURPOSES