

PACKAGE INSERT

Infectious Pancreatic Necrosis Virus - Infectious Salmon Anaemia Virus, Killed Virus, *Aeromonas salmonicida* – *Moritella viscosa* – *Vibrio anguillarum* O1 & O2a – *Vibrio salmonicida* Bacterin

ALPHA JECT micro® 7 ISA

Emulsion for injection for Atlantic salmon

For veterinary use only

Description:

A furunculosis, vibriosis, cold water vibriosis, winter ulcer, Infectious Pancreatic Necrosis (IPN) and Infectious Salmon Anaemia (ISA) vaccine containing formaldehyde inactivated cultures of *Aeromonas salmonicida* subsp. *salmonicida*, *Vibrio anguillarum* serotypes O1 and O2a, *Vibrio salmonicida*, *Moritella viscosa*, IPN virus serotype Sp. and ISA virus.

Indications:

ALPHA JECT micro 7 ISA is recommended for use as an aid in the prevention of furunculosis caused by *Aeromonas salmonicida*, vibriosis caused by *Vibrio anguillarum* serotypes O1 and O2a, cold water vibriosis caused by *Vibrio salmonicida*, winter ulcers caused by *Moritella viscosa*, Infectious Pancreatic Necrosis disease caused by IPN virus and Infectious Salmon Anaemia disease caused by EU isolates of ISA virus in healthy Atlantic salmon. Significant reduction in mortality numbers has been documented under laboratory conditions in vaccinated fish after challenge with North American ISAV isolates.

Directions for Use:

Bring the vaccine slowly to 15-20°C by keeping it at room temperature overnight. Ensure a homogenous emulsion prior to use by squeezing and shaking the vaccine bag for approx. 2 minutes. Vaccinate healthy fish, 25 g or larger, intraperitoneally with a 0.05 mL dose of vaccine per fish. It is recommended that the fish being starved for a minimum of 48 hours and anaesthetized prior to vaccination. Deposit the entire dose into the abdominal cavity in order to reduce the risk of side effects. The injection needle should be 0.7 mm or 0.6 mm diameter and have an appropriate length to penetrate the abdominal wall by 1-2 mm. The entire needle should be inserted into the midline about one, to one and a half pelvic fin lengths anterior to the base of the pelvic fin.

Cautions:

1. Vaccinate healthy fish only.
2. Do not administer to fish which have already received this vaccine.
3. Vaccinate only fish intended for broodstock based on a benefit-risk assessment performed by the responsible veterinarian. Avoid vaccination during smoltification.
4. Do not vaccinate within 60 days prior to slaughter.
5. A period of 520 degree days for the bacterial antigens, 600 degree days for IPNV, 500 degree days for ISAV isolates of European origin and 770 degree days for ISAV isolates of North American origin following the vaccination is recommended before fish are transferred to sea.
6. As a general precaution it is recommended to perform vaccination at water temperature of 15°C or below. Do not vaccinate at water temperatures below 1°C or above 18°C.

7. Only administer if the vaccine appears as a homogeneous, white to cream colored emulsion. The vaccine should not be used if the vaccine shows signs of a brownish water phase in the bottom of the container. Contact the distributor for further advice.
8. Ensure that all vaccination equipment is sanitized before use.
9. Ensure that the method of restraint, handling and administration minimizes the risk of accidental self-injection. This product is a mineral oil-based compound. Accidental self-injection may result in severe pain and swelling and requires prompt medical attention.
10. Side effects in the form of visceral adhesions and pigmentation may be observed after vaccination. A transient growth rate reduction due to the stress of handling may be noted following vaccination.
11. The severity of adverse reactions may be influenced by different factors such as sanitation, vaccination technique, fish size at vaccination and water temperature during vaccination and in the first 6-12 weeks after vaccination. Small fish and high water temperature may increase the severity of adverse reactions.
12. No information is available on the compatibility of this vaccine with any other veterinary medicinal product. A decision to use this vaccine before or after any other veterinary medicinal product therefore needs to be made on a case by case basis.
13. Dispose of any unused product according to local biomedical waste disposal requirements.
14. Keep out of the reach of children.

To the user:

This product contains mineral oil. Accidental injection/self-injection may result in severe pain and swelling, particularly if injected into a joint or finger, and in rare cases could result in the loss of the affected finger if prompt medical attention is not given. 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 physician:

This product contains mineral oil. Even if small amounts have been injected, accidental injection with this product can cause intense swelling, which may, for example, result in ischaemic necrosis and even 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.

Repeated self-injections may aggravate the effects or cause anaphylactic shock.

Precautions:

Store at 2-8°C (35-46°F). Do not freeze. Protect from light.

Shelf life after first opening the immediate packaging: 10 hours

Presentation:

ALPHA JECT micro 7 ISA is supplied in 250 mL (5 000 doses) and 500 mL (10 000 doses) UVO injection bags.

Manufactured by: PHARMAQ AS, Overhalla, Norway

Distributed by: Zoetis Canada Inc., Kirkland, Quebec