

ALPHA JECT® 2-2 Emulsion for injection



Presentation

An adjuvanted water in oil emulsion vaccine for injection consisting of inactivated cultures of *Aeromonas salmonicida* subsp. *salmonicida* and infectious pancreatic necrosis virus (IPNV), and adjuvant and emulsifiers.

Uses

Prevents mortality of the disease caused by *Aeromonas salmonicida* (furunculosis) and reduces mortality of the disease caused by IPNV (infectious pancreatic necrosis) in Atlantic salmon of a minimum weight of 39 g. The onset of immunity occurs no later than 600 degree days from vaccination. The protection against *Aeromonas salmonicida* lasts for at least 12 months post vaccination. The duration of protection for IPNV is unknown. Efficacy has not been fully evaluated.

Dosage and administration

The fish must be anaesthetised prior to injection. Each fish should be given a single 0.1ml dose of vaccine by intraperitoneal injection. To reduce the risk of adverse reactions, it is important to deposit the entire dose in the abdominal cavity. The injection needle should have appropriate diameter, and 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.

Contra-indications, Warnings, etc

Contra-indications: Do not use in fish intended for broodstock.

Warnings: Do not administer this product to fish which have already received this vaccine. Fish with clinical signs of disease must not be vaccinated. Do not vaccinate at water temperatures below 1°C and above 18°C. Temperatures close to 18°C are suboptimal for Atlantic salmon, thus vaccination should preferably be performed at water temperatures of 15°C or below. Avoid vaccination the last 4 weeks prior to sea transfer and during smoltification. The severity of the undesirable effects is among other things, dependent on hygiene, vaccination technique, size of the fish at vaccination and water temperature during vaccination.

Keep out of the reach and sight of children. For animal treatment only.

Adverse reactions: Adverse reactions in the form of visceral adhesions and pigmentation occur. Adhesions between the abdominal wall and the viscera in addition to pigmentation on the viscera and abdominal wall are normally seen. Vaccinated fish show some growth retardation compared to non-vaccinated fish.

Short term (21 days) safety in 15g fish has been demonstrated. The severity of long term lesion development in 15g fish is unknown. Following injection of an overdose, there is an increased risk of development of more severe lesions in the abdominal cavity, characterised by more severe pigmentation and adhesions between the abdominal wall and viscera

Withdrawal period: Zero days.



Operator warnings: Ensure that the method of restraint, handling and administration e.g. by the use of guarded needles (such as a protecting device attached to the syringe providing a shield against the tip of the needle), minimises the risk of accidental self-injection.

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 insert 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.

Pharmaceutical precautions

Store and transport at 2 to 8°C. Do not freeze. Protect from light.

The vaccine should be left to slowly reach 15 C - 20°C by keeping it at room temperature. The vaccine should be well shaken prior to use. Only administer if the vaccine appears as a homogenous, white to cream coloured emulsion after shaking. If the vaccine shows signs of a brownish water phase in the bottom of the container, it should not be used for vaccination. Contact the distributor for further advice.

Once opened, use as soon as possible. Do not re use opened containers.

Ensure the vaccination equipment is disinfected before use.

Administration of the vaccine must be performed using an injection system that prevents back flush of the vaccine into the vaccine tube/container.

Legal category

POM

Package quantities

0.5 litre injection bags

Further information

UAny unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

No information is available on the safety and efficacy from concurrent use of this vaccine with any other. It is therefore recommended that no other vaccines should be administered within 14 days before or after vaccination with this product.

Occasional mortality may occur if individuals fail to respond or the immune system is suppressed by concurrent infections, poor nutritional status, genetic factors, smoltification or other stressful environmental conditions.



Marketing authorisation number

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Marketing Authorisation Holder

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