PACKAGE LEAFLET:

ALPHA JECT micro 1 Noda, emulsion for injection for sea bass

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder and manufacturer responsible for batch release:

PHARMAQ AS
7863 Overhalla
Norway

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

ALPHA JECT micro 1 Noda, emulsion for injection for sea bass.

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

Each dose (0.05 ml) contains:
Active substance:
Inactivated Red-spotted Grouper Nervous Necrosis Virus (RGNNV) strain ALV1107
≥ 0.07 antigenicity units[1]

[1] quantity of antigen measured in vaccine (short version AgU)

Adjuvant:
Liquid paraffin (mineral oil) 23 mg

Emulsion for injection.
White to cream coloured homogeneous emulsion when shaken.

4. INDICATION(S)

For active immunisation of sea bass to reduce mortality caused by Red-spotted Grouper Nervous Necrosis Virus (RGNNV).

Onset of immunity: 466 degree days.

Duration of immunity: 1 year

5. CONTRAINDICATIONS

None.

6. ADVERSE REACTIONS

Oil adjuvants are associated with increased risk of local reactions in the form of adhesions in the abdomen and pigmentation on the viscera in fishes.

Very common (> 1/10):
- At 12 months, mild abdominal adhesions have been shown in laboratory studies.
- At 12 months, small amounts of melanin, seen as few spots covering very limited areas of the viscera often close to the injection site have been observed in laboratory studies.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports)

If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

7. TARGET SPECIES

Sea bass (*Dicentrarchus labrax*)

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Intraperitoneal use.

The recommended dose is 0.05 ml per fish of a minimum weight of 12 g. The vaccine should be administered by intraperitoneal (IP) injection.

9. ADVICE ON CORRECT ADMINISTRATION

The fish should be anaesthetised prior to injection. It is recommended to starve the fish for a minimum of 24 hours before vaccination.

The vaccine should be left to slowly reach 15 – 20 °C by keeping it at room temperature. 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. The vaccine should be well shaken prior to use. Only administer if the vaccine appears as a homogenous, white to cream coloured emulsion.

To reduce the risk of adverse reactions, it is important to deposit the entire dose in the abdominal cavity. The injection needle used should have 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 length posterior to the base of the pelvic fin.

After vaccination the equipment used for vaccination should be thoroughly cleaned.

10. WITHDRAWAL PERIOD

Zero degree days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Store and transport refrigerated (2 °C – 8 °C).

Do not freeze.
Protect from light.

Do not use this veterinary medicinal product after the expiry date which is stated on the label.

Shelf life after first opening the container: 10 hours.

12. SPECIAL WARNING(S)

Special warnings for each target species:
Vaccinate healthy animals only.

Special precautions for use in animals:
Due to handling, vaccination may be followed by temporary reduced appetite.

Fish with clinical symptoms of disease should not be vaccinated.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

The use of needle guards is recommended in order to reduce the risk of accidental self-injection during manual vaccination.

To the user:
This veterinary medicinal 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 veterinary medicinal 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 veterinary medicinal 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.

Pregnancy/Lactation/Lay/Fertility:
The safety of the veterinary medicinal product has not been established for use in broodstock, and vaccination of broodstock should be subject to a risk benefit evaluation of the prescribing veterinarian.

Interaction with other medicinal products and other forms of interaction:
No information is available on the safety and efficacy of this vaccine when used 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.

Overdose (symptoms, emergency procedures, antidotes):
Effects of an overdose have not been investigated as it is not required for inactivated vaccines.

Incompatibilities:
Do not mix with any other veterinary medicinal product.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

06/2023

15. OTHER INFORMATION

Package sizes: 250 ml, 500 ml and 10 x 500 ml.

Not all pack sizes may be marketed

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder: