1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

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.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

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

4. CLINICAL PARTICULARS

4.1 Target species

Sea bass (*Dicentrarchus labrax*)

4.2 Indications for use, specifying the target species

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

4.3 Contraindications

None.

4.4 Special warnings for each target species

Vaccinate healthy animals only.

4.5 Special precautions for use

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.

4.6 Adverse reactions (frequency and seriousness)

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)

4.7 Use during pregnancy, lactation or lay

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.

4.8 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.

4.9 Amounts to be administered and administration route

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. 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.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

Effects of an overdose have not been investigated as it is not required for inactivated vaccines.

4.11 Withdrawal period(s)

Zero degree days.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Immunologicals for pisces, others
ATCvet code: QI10X

Stimulates development of active immunity in sea bass against Red-spotted Grouper Nervous Necrosis Virus.
The occurrence of false positive PCR results due to vaccination when screening for presence of VNN virus in brain tissue by Real Time RT-PCR is highly unlikely.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Liquid paraffin (mineral oil)
Sorbitan oleate
Polysorbate 80
Water for injections

The vaccine may contain formaldehyde as a residue after inactivation.

6.2 Major incompatibilities

Do not mix with any other veterinary medicinal product.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 30 months
Shelf life after first opening the immediate packaging: 10 hours

6.4. Special precautions for storage

Store and transport refrigerated (2 °C - 8 °C).
Do not freeze.
Protect from light.

6.5 Nature and composition of immediate packaging

Injection bags made of a multilayer plastic foil. The giving port is closed with a rubber stopper. The vaccine bag is packed in a zip-lock bag or cardboard box.
Package sizes: 250 ml, 500 ml and 10 x 500 ml

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

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

7. MARKETING AUTHORISATION HOLDER

PHARMAQ AS
7863 Overhalla
Norway

8. MARKETING AUTHORISATION NUMBER(S)

MA no.:

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: DD month YYYY

10 DATE OF REVISION OF THE TEXT

06/2023

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.