[Version 8.2,01/2021]

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ICTHIOVAC VNN, emulsion for injection for sea bass.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose (0.1 ml) contains:

Active substance:
Inactivated *Betanodavirus* strain 1103…….. RP* ≥ 1.3

*RP: Relative Potency determined by ELISA, using a reference vaccine demonstrated to be efficacious.

Adjuvant:
Montanide ……..63.63 mg

Excipients:
Sodium methyl parahydroxybenzoate …….. 0.18 mg
Sodium propyl parahydroxybenzoate …… 0.02 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Ivory coloured homogeneous emulsion for injection.

4. CLINICAL PARTICULARS

4.1 Target species

Sea bass (*Dicentrarchus labrax*)

4.2 Indications for use, specifying the target species

For the active immunisation of sea bass to reduce the mortality caused by Viral Nervous Necrosis following infection by *Betanodavirus*.

Onset of immunity: 42 days after vaccination at 22 ºC (924 degree days).

Duration of immunity: 18 months.

4.3 Contraindications

None.

4.4 Special warnings for each target species

Vaccinate healthy animals only.
Fish shall not be stressed during 48 hours before vaccination and 15 days thereafter.
Culture water temperature during vaccination shall be equal to or slightly lower than the optimal culture temperature for sea bass (between 17 and 22 ºC).

4.5 Special precautions for use

Special precautions for use in animals
Do not vaccinate unhealthy animals or carriers of pathogenic microorganisms.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
In case of accidental self-administration, seek medical advice immediately and show the package leaflet or the label to the physician.

To the user:
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:
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)

Adverse reactions observed at necropsy 21 days after vaccination in laboratory safety studies:
- Very common: Fish may show slight adhesions and vesicles of encapsulated vaccine. None of these findings are of clinical relevance and they usually resolve spontaneously.

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 and efficacy has not been studied in breeders, therefore, the vaccination of breeders is not recommended.

4.8 Interaction with other medicinal products and other forms of interaction

No information is available of 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

Administration by intraperitoneal injection of one dose of 0.1 ml/fish, when fish weight is approximately 15 g.

Fish must be anaesthetised prior to vaccination.

The usage of vaccination guns with 23G needles is recommended. The needle should penetrate the abdominal wall minimum by 1 mm, to deposit the entire dose in the abdominal cavity.

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

Inactivated vaccine for which study of the safety of an overdose is not required.

4.11 Withdrawal period(s)

Zero degree days.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Immunologicals for pisces, others.

ATC vet code: QI10X.

To stimulate active immunity in sea bass against *Betanodavirus*.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Montanide
Sodium methyl parahydroxybenzoate
Sodium propyl parahydroxybenzoate
Disodium phosphate dodecahydrate
Potassium dihydrogen phosphate
Sodium chloride
Potassium chloride
Water for injections

6.2 Major incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 24 months.
Shelf life after first opening the immediate packaging: 10 hours.

6.4. Special precautions for storage

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

6.5 Nature and composition of immediate packaging

500 ml (5000 doses) high density polyethylene bottles closed with nitrile-chlorobutyl rubber stoppers and aluminium caps.

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

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8. MARKETING AUTHORISATION NUMBER(S)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

10 DATE OF REVISION OF THE TEXT

PROHIBITION OF SALE, SUPPLY AND/OR USE

Conditions of dispensing: subject to veterinary prescription.
Conditions of administration: subject to control or supervision of the veterinary surgeon.