**PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE - <u>COMBINED LABEL AND PACKAGE LEAFLET</u>**

**{NATURE/TYPE}**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

**AQUATRECK VP INJ** emulsion for injection for sea bass

## 2. COMPOSITION

Each 0.1 mL dose contains:

**Active substances:**

*Vibrio anguillarum* serotype O1, strain AT-VA1/19, Inactivated ..... $RPS_{60} \geq 75\%$ (*)
*Photobacterium damselae* subsp. *piscicida*, strain AT-PDP5/19, Inactivated ..... $RPS_{60} \geq 75\%$ (*)

(*) $RPS_{60}$: Relative percentage survival based on challenge studies and expressed as [(1- $MV_{60}$ / 60) *100]. Where $MV_{60}$ is the percentage mortality in the vaccinated group at 60% mortality in controls and 60 is the mortality of controls.

**Adjuvant**:

Montanide ISA 763 A VG..... 0.07 mL

White emulsion.

## 3. PACKAGE SIZE

500 mL

## 4. TARGET SPECIES

Sea bass (*Dicentrarchus labrax*).

## 5. INDICATIONS FOR USE

**Indications for use**
For the active immunization of sea bass to reduce mortality caused by infection *Vibrio anguillarum* serotype O1 and *Photobacterium damselae* subsp. *piscicida*.

<u>Onset of immunity</u>:

21 days at 23ºC (483 degree days) for *Vibrio anguillarum* serotype O1, strain AT-VA1/19.
28 days at 23ºC (644 degree days) for *Photobacterium damselae* subsp. *piscicida*, strain AT-PDP5/19.

<u>Duration of immunity</u>: 201 days at 23ºC (4,623 degree days)

## 6. CONTRAINDICATIONS

**Contraindications**
None.

## 7. SPECIAL WARNINGS

**Special warnings**

Special warnings:

Vaccinate healthy animals only.

Special precautions for safe use in the target species:

Not applicable.

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

In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

Special precautions for the protection of the environment:

Not applicable.

Fertility:

The safety of the veterinary medicinal product in future broodstock has not been established.

Interactions 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:

Not known.

Special restrictions for use and special conditions for use:

Major incompatibilities:

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

## 8. ADVERSE EVENTS

**Adverse events**

Sea bass (*Dicentrarchus labrax*).

| | |
|---|---|
| Very common<br>(>1 animal / 10 animals treated): | Adhesion in fish [1,2,3]<br>Weight loss [4] |

(1) Soft, localised peritoneal adhesions of the visceral peritoneum. Presence of few small, pin point, mostly non-pigmented (creamy coloured) peritoneal granulomatous lesions in the form of tiny nodules.
(2) Soft but widespread adhesions of the visceral peritoneum. Presence of few small, pin point, peritoneal nodules, rarely > 1 mm in diameter, mostly non-pigmented (creamy coloured).
(3) With common frequency, soft to moderately hard widespread adhesions of the visceral peritoneum. Presence of many peritoneal nodules of variable sizes, mostly small pin point, but also larger > 2 mm in diameter, in the majority non-pigmented (creamy coloured), but some pigmented (orange, grey, brownies to black).
(4) It may occur up to 120 days post-vaccination.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed on this label, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details on this label, or via your national reporting system {national system details}.

## 9. DOSAGE FOR EACH TARGET SPECIES, ROUTES AND METHOD OF ADMINISTRATION

**Dosage for each species, routes and method of administration**
For intraperitoneal use.
Administer one dose of 0.1 mL by intraperitoneal injection.

## 10. ADVICE ON CORRECT ADMINISTRATION

**Advice on correct administration**
Place the container at ambient temperature approximately 20 min before use and shake well prior to vaccination.
Vaccination is recommended for sea bass above 10 grams.
Fish that are intended to be vaccinated should not be fed 24 hours prior to vaccination.
Anesthetize fish before vaccination.
The vaccination temperature should be similar to the optimal cultivation temperature of the species.

## 11. WITHDRAWAL PERIODS

**Withdrawal periods**
Zero degree days.

## 12. SPECIAL STORAGE PRECAUTIONS

**Special storage precautions**

Keep out of the sight and reach of children.

Store and transport refrigerated (2 ºC – 8 ºC).
Do not freeze.
Protect from light.

Do not use this veterinary medicinal product after the expiry date which is stated on the label. The expiry date refers to the last day of that month.

## 13. SPECIAL PRECAUTIONS FOR DISPOSAL

**Special precautions for disposal**

Medicines should not be disposed of via wastewater <or household waste>.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

Ask your <veterinary surgeon> <or> <pharmacist> how to dispose of medicines no longer required.

## 14. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

**Classification of veterinary medicinal products**

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

## 15. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

**Pack sizes**

Bottle containing 500 mL.

## 16. DATE ON WHICH THE LABEL WAS LAST REVISED

**Date on which the label was last revised**

Detailed information on this veterinary medicinal product is available in the Union Product Database.

## 17. CONTACT DETAILS

**Contact details**

Marketing authorisation holder and contact details to report suspected adverse reactions:
AQUATRECK Animal Health, S.L.
A Relva s/n – Torneiros
36410 O Porriño
Pontevedra
Spain
Tel: +34 986 33 04 00

Manufacturer responsible for batch release:
CZ Vaccines S.A.U.

A Relva s/n – Torneiros
36410 O Porriño
Pontevedra
Spain

## 18. OTHER INFORMATION

## 19. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

## 20. EXPIRY DATE

Exp {mm/yyyy}

Shelf life after first opening the immediate packaging: use immediately.

## 21. BATCH NUMBER

Lot {number}