

**ANNEX I**  
**SUMMARY OF PRODUCT CHARACTERISTICS**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

AQUATRECK VP INJ emulsion for injection for sea bass

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 0.1 mL dose contains:

### Active substances:

*Vibrio anguillarum* serotype O1, strain AT-VA1/19, Inactivated .....RPS<sub>60</sub> ≥ 75% (\*)  
*Photobacterium damsela* subsp. *piscicida*, strain AT-PDP5/19, Inactivated .....RPS<sub>60</sub> ≥ 75% (\*)

(\*) RPS<sub>60</sub>: Relative percentage survival based on challenge studies and expressed as  $[(1 - MV_{60} / 60) * 100]$ . Where MV<sub>60</sub> 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

### Excipient:

<b>Qualitative composition of excipients and other constituents</b>
Leibovitz without Phenol Red medium

White emulsion.

## 3. CLINICAL INFORMATION

### 3.1 Target species

Sea bass (*Dicentrarchus labrax*).

### 3.2 Indications for use for each target species

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

#### Onset of immunity:

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

Duration of immunity: 201 days at 23°C (4,623 degree days)

### 3.3 Contraindications

None.

### 3.4 Special warnings

Vaccinate healthy animals only.

### 3.5 Special precautions for use

#### 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.

### 3.6 Adverse events

Sea bass (*Dicentrarchus labrax*).

Very common (>1 animal / 10 animals treated):	Adhesion in fish <sup>1,2,3</sup> Weight loss <sup>4</sup>
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<sup>(1)</sup> 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.

<sup>(2)</sup> 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).

<sup>(3)</sup> 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).

<sup>(4)</sup> It may occur up to 120 days post-vaccination.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

### 3.7 Use during pregnancy, lactation or lay

#### Fertility:

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

### 3.8 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.

### 3.9 Administration routes and dosage

For intraperitoneal use.

Administer one dose of 0.1 mL by intraperitoneal injection.

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.

### **3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)**

Not known.

### **3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance**

### **3.12 Withdrawal periods**

Zero degree days.

## **4. IMMUNOLOGICAL INFORMATION**

### **4.1 ATCvet code: QI10X**

The vaccine stimulates active immunization of sea bass against *Vibrio anguillarum* serotype O1 and *Photobacterium damsela* subsp. *piscicida*.

## **5. PHARMACEUTICAL PARTICULARS**

### **5.1 Major incompatibilities**

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

### **5.2 Shelf life**

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.  
Shelf life after first opening the immediate packaging: use immediately.

### **5.3 Special precautions for storage**

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

### **5.4 Nature and composition of immediate packaging**

High density polyethylene (HDPE) bottles of 500 mL with nitrile rubber stopper and aluminium seal.

Package size: Bottle containing 500 mL.

### **5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products**

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 national collection systems applicable to the veterinary medicinal product concerned.

**6. NAME OF THE MARKETING AUTHORISATION HOLDER**

AQUATRECK Animal Health, S.L.

**7. MARKETING AUTHORISATION NUMBER(S)**

**8. DATE OF FIRST AUTHORISATION**

**9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS**

**10. 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 \(https://medicines.health.europa.eu/veterinary\)](https://medicines.health.europa.eu/veterinary).