*[Version 8.1,01/2017]*

**ANNEX I**

**SUMMARY OF PRODUCT CHARACTERISTICS**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ICTHIOVAC-PD PASTEURELLOSIS DORADA Concentrate for dip suspension for gilthead.

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose contains:

**Active substance:**
Inactivated *Photobacterium damselae* subsp. *piscicida** RPS** ≥ 60%
(*) Strains DI 21 and It-1
(**) RPS: Relative Percentage of Survival after intraperitoneal challenge in gilthead.

**Excipients:**
For the full list of excipients, see section 6.1.

## 3. PHARMACEUTICAL FORM

Concentrate for dip suspension.
Yellow-brownish suspension.

## 4. CLINICAL PARTICULARS

### 4.1 Target species

Gilthead (*Sparus aurata)*.

### 4.2 Indications for use, specifying the target species

For active immunization of gilthead to reduce the mortality caused by infection by *Photobacterium damselae,* subsp. *piscicida* (Pasteurellosis).

Onset of immunity: 28 days from vaccination (20-23ºC).
Duration of immunity: 5 months from vaccination.

### 4.3 Contraindications

None.

### 4.4 Special warnings for each target species

- It is necessary to maintain a strong aeration during the vaccination process, and monitor on the oxygen level in the vaccinal solution.
- Fish should not be put under stress for 48 hours prior to vaccination and for the 15 days following vaccination.
- Water culture temperature for vaccination should be kept at the same or slightly lower temperature than the optimal one for the growth of gilthead.
- Vaccinate healthy animals only.

## 4.5 Special precautions for use

Special precautions for use in animals
Not applicable.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
Not applicable.

## 4.6 Adverse reactions (frequency and seriousness)

None.

## 4.7 Use during pregnancy, lactation or lay

Do not use in breeding animals.

## 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

The vaccine is administrated by dipping of fish after dissolution in sea water.

Prepare a dip suspension by diluting the vaccine in water at a rate 1:10 (vaccine:water) or 1:500 (vaccine:water) depending whether vaccination is by dip immersion or by bath immersion respectively and do not overpass 100 kg of fish per litre of vaccine.

**Vaccination by dip immersion**: introduce the fish into the dipsuspension (dilution 1:10) in a 60 second bath. Do not overpass 0.5 kg of fish per litre of dipsuspension. Discard the dip suspension after 20 immersions.

**Vaccination by bath immersion:** add the vaccine to the culture tank considering the dilution factor 1:500 (vaccine:water). Previously, the water level will be lowered to a minimum. The vaccination period will last one hour. Do not overpass 100 kg of fish per 500 litres of dip suspension. Thereafter the original water volume of the tank and its recirculation will be restored.

Recommended vaccination programme: a single vaccination of fish from 1 to 2 g of body weight.

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

None.

## 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 against *Photobacterium damselae* subsp. *piscicida* in giltheads.

## 6. PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Culture media:
Heart infusion
Sodium chloride
Water, highly purified

### 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: 2 years.
Shelf life after first opening the immediate packaging: use immediately.
Shelf life after dilution according to directions: use immediately.

### 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

The container consists of polypropylene (PP) bottled of 1,000 ml, 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

Date of first authorisation: {DD/MM/YYYY}.
Date of last renewal: {DD/MM/YYYY}.

## 10 DATE OF REVISION OF THE TEXT

{MM/YYYY}

## PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.