[Version 9,03/2022] corr. 11/2022

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:

Qualitative composition of excipients and other constituents
Heart infusion
Sodium chloride
Water, highly purified

Yellow-brownish suspension.

3. CLINICAL INFORMATION

3.1 Target species

Gilthead (*Sparus aurata*).

3.2 Indications for use for each 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.

3.3 Contraindications

None.

3.4 Special warnings

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.

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:

Not applicable.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

None known.

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 section 'Contact details' of the package leaflet.

3.7 Use during pregnancy, lactation or lay

Fertility:
Do not use in breeding animals.

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

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 dip suspension (dilution 1:10) in a 60 second bath. Do not overpass 0.5 kg of fish per litre of dip suspension. 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.

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

None.

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

Not applicable.

3.12 Withdrawal periods

Zero degree days.

4. IMMUNOLOGICAL INFORMATION

4.1 ATCvet code: QI10X.

To stimulate active immunity against *Photobacterium damselae* subsp. *piscicida* in giltheads.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product.

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.
Shelf life after dilution according to directions: 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

The container consists of polypropylene (PP) bottled of 1 000 ml, rubber stoppers and aluminium caps.

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

LABORATORIOS HIPRA, S.A.

7. MARKETING AUTHORISATION NUMBER(S)

To be completed nationally.

8. DATE OF FIRST AUTHORISATION

To be completed nationally.

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

To be completed nationally.

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).

ANNEX III

LABELLING AND PACKAGE LEAFLET

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

1 000 ml bottles

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. COMPOSITION

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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.

Yellow-brownish suspension.

3. PACKAGE SIZE

1 000 ml

4. TARGET SPECIES

Gilthead (*Sparus aurata*)

5. INDICATIONS FOR USE

Indications for use

For active immunization of gilthead seabream 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.

6. CONTRAINDICATIONS

Contraindications

None.

7. SPECIAL WARNINGS

Special warnings

<u>Special warnings</u>:

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.

Fertility:

Do not use in breeding animals.

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.

Major incompatibilities:

Do not mix with any other veterinary medicinal product.

8. ADVERSE EVENTS

Adverse events

None known.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in 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

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 dip suspension (dilution 1:10) in a 60 second bath. Do not overpass 0.5 kg of fish per litre of dip suspension. 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.

10. ADVICE ON CORRECT ADMINISTRATION

Advice on correct administration

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 °C – 8 °C).
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 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.

15. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

To be completed nationally.

Pack sizes

1 000 ml

16. DATE ON WHICH THE LABEL WAS LAST REVISED

Date on which the label was last revised

To be completed nationally.

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

17. CONTACT DETAILS

Contact details

Marketing authorisation holder and manufacturer responsible for batch release and contact details to report suspected adverse reactions:

LABORATORIOS HIPRA, S.A.
Avda. La Selva, 135
17170 Amer (Girona) SPAIN
Tel. +34 972 43 06 60

Local representatives and contact details to report suspected adverse reactions:

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder listed below.

To be completed nationally.

18. OTHER INFORMATION

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.
Shelf life after dilution according to directions: use immediately.

21. BATCH NUMBER

Lot {number}