

A. LABELLING

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE – COMBINED LABEL AND PACKAGE LEAFLET

1,000 ml

1. Name and address of the marketing authorisation holder and of the manufacturing authorisation holder responsible for batch release, if different

Marketing authorisation holder and manufacturer responsible for batch release:

LABORATORIOS HIPRA, S.A.
Avda. la Selva, 135
17170 Amer (Girona)
SPAIN

2. Name of the veterinary medicinal product

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

3. Statement of the active substance(s) and other ingredients

Each dose contains:

Active substance:

Inactivated *Photobacterium damsela* subsp. *piscicida** RPS** \geq 60%

(*) Strains DI 21 and It-1

(**) RPS: Relative Percentage of Survival after intraperitoneal challenge in gilthead.

4. Pharmaceutical form

Concentrate for dip suspension.
Yellow-brownish suspension.

5. Package size

1,000 ml

6. Indication(s)

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

Onset of immunity: 28 days from vaccination (20-23°C).

Duration of immunity: 5 months from vaccination.

7. Contraindications

None.

8. Adverse reactions

None.

If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

Alternatively you can report via your national reporting system {national system details}.

9. Target species

Gilthead (*Sparus aurata*).

10. Dosage for each species, route(s) and method of administration

The vaccine is administered 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.

11. Advice on correct administration

12. Withdrawal period(s)

Withdrawal period(s): Zero degree days.

13. Special storage precautions

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.

14. Special warning(s)

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.

Fertility: Do not use in breeding animals.

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.

Incompatibilities:

Do not mix with any other veterinary medicinal product.

15. Special precautions for the disposal of unused products or waste materials, if any

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

Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

16. Date on which the package leaflet was last approved

17. Other information

Package sizes:

1,000 ml

18. The words “For animal treatment only” and conditions or restrictions regarding supply and use, if applicable

For animal treatment only - to be supplied only on veterinary prescription.

19. The words “Keep out of the sight and reach of children”

Keep out of the sight and reach of children.

20. Expiry date

EXP {month/year}

Once opened use immediately.

Shelf life after dilution according to directions: use immediately.

21. Marketing authorisation number(s)

22. Manufacturer’s batch number

Batch/Lot {number}