[Version 9,03/2022]

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ICTHIOVAC VR/PD, emulsion for injection for sea bass.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose of 0.1 ml contains:

Active substances:
Inactivated *Photobacterium damselae* subsp. *piscicida* DI 21 ……...….. RPS ≥ 60% (*)
Inactivated *Listonella anguillarum* serotype O1 …….. RPS ≥ 75% (*)
Inactivated *Listonella anguillarum* serotype O2α …… RPS ≥ 75% (*)
Inactivated *Listonella anguillarum* serotype O2β…….…… RPS ≥ 75% (*)

(*) RPS: Relative Percentage of Survival in sea bass after intraperitoneal challenge

Adjuvant:
Montanide ……..63.63 mg

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Sodium methyl parahydroxybenzoate	0.18 mg
Sodium propyl parahydroxybenzoate	0.02 mg
Disodium phosphate dodecahydrate	
Potassium dihydrogen phosphate	
Sodium chloride	
Potassium chloride	
Water for injections	

Ivory emulsion homogenous after shaking.

3. CLINICAL INFORMATION

3.1 Target species

Sea Bass (*Dicentrarchus labrax*)

3.2 Indications for use for each target species

For the active immunisation of sea bass to reduce the mortality caused by infection by *Photobacterium damselae,* subsp. *piscicida* (pasteurellosis) and by infection by *Listonella anguillarum* serotypes O1, O2α and O2β.

Onset of immunity: 42 days after vaccination at 19 – 21 ºC (798 – 882 degree days).
Duration of immunity: not established.

3.3 Contraindications

None.

3.4 Special warnings

Fish shall not be stressed during 48 hours before vaccination and 15 days thereafter.

Culture water temperature during vaccination shall be equal to or slightly lower than the optimal culture temperature for sea bass (between 17 and 22 ºC).

3.5 Special precautions for use

Special precautions for safe use in the target species:
Do not vaccinate unhealthy animals or carriers of pathogenic microorganisms.

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.
To the user:
This veterinary medicinal product contains mineral oil. Accidental injection/self-injection may result in severe pain and swelling, particularly if injected into a joint or finger, and in rare cases could result in the loss of the affected finger if prompt medical attention is not given. If you are accidentally injected with this veterinary medicinal product, seek prompt medical advice even if only a very small amount is injected and take the package leaflet with you. If pain persists for more than 12 hours after medical examination, seek medical advice again.

To the physician:
This veterinary medicinal product contains mineral oil. Even if small amounts have been injected, accidental injection with this product can cause intense swelling, which may, for example, result in ischaemic necrosis and even the loss of a digit. Expert, PROMPT, surgical attention is required and may necessitate early incision and irrigation of the injected area, especially where there is involvement of finger pulp or tendon.

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):	Very slight adhesions close to the injection site[1,2,3]
Common (1 to 10 animals / 100 animals treated):	Minor adhesions in the abdominal wall[2,3]

[1]Unlikely to be noticed when evisceration.
[2]Any observed adhesion disappears during the fattening period.
[3]Adverse events observed at necropsy 21 days after vaccination in laboratory safety studies.

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 the national competent authority via the national reporting system. See also the last section of the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Fertility:
The safety and efficacy have not been studied in breeders, therefore, the vaccination of breeders is not recommended.

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

Administration by intraperitoneal injection in one dose of 0.1 ml/fish, when fish weight is approximately 15 g.

Fish must be anaesthetised prior to vaccination.

The usage of vaccination guns with 23G needles is recommended. The needle should penetrate the abdominal wall minimum by 1 mm, to deposit the entire dose in the abdominal cavity.

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

Inactivated vaccine for which study of the safety of an overdose is not required.

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 in sea bass against *Photobacterium damselae subsp. piscicida* and *Lisonella anguillarum*.

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: 24 months
Shelf life after first opening the immediate packaging: 10 hours

5.3 Special precautions for storage

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

5.4 Nature and composition of immediate packaging

500 ml high density polyethylene bottles closed with rubber stoppers and aluminium caps.

5.5 Special precautions for the disposal of unused veterinary medicinal product 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)

8. DATE OF FIRST AUTHORISATION

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.

ANNEX III

LABELLING AND PACKAGE LEAFLET

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

500 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ICTHIOVAC VR/PD, emulsion for injection for sea bass.

2. COMPOSITION

Each dose of 0.1 ml contains:

Active substance:
Inactivated *Photobacterium damselae* subsp. *piscicida* DI 21 ……..….... RPS ≥ 60% (*)
Inactivated *Listonella anguillarum* serotype 01 ……..…..… RPS ≥ 75% (*)
Inactivated *Listonella anguillarum* serotype 02α ……..… RPS ≥ 75% (*)
Inactivated *Listonella anguillarum* serotype 02β ……..… RPS ≥ 75% (*)

(*) RPS: Relative Percentage of Survival in sea bass after intraperitoneal challenge

Adjuvant:
Montanide ……..……..……63.63 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Sodium methyl parahydroxybenzoate	0.18 mg
Sodium propyl parahydroxybenzoate	0.02 mg
Disodium phosphate dodecahydrate	
Potassium dihydrogen phosphate	
Sodium chloride	
Potassium chloride	
Water for injections	

Ivory emulsion homogenous after shaking.

3. PACKAGE SIZE

500 ml

4. TARGET SPECIES

Sea Bass (*Dicentrarchus labrax*)

5. INDICATIONS FOR USE

Indications for use

For the active immunisation of sea bass to reduce the mortality caused by infection by *Photobacterium damselae,* subsp*. piscicida* (pasteurellosis) and by infection by *Listonella anguillarum* serotypes O1, O2α and O2β.
Onset of immunity: 42 days after vaccination at 19 – 21 ºC (798 – 882 degree days).
Duration of immunity: not established.

6. CONTRAINDICATIONS

Contraindications

None.

7. SPECIAL WARNINGS

Special warnings

Special warnings:

Fish shall not be stressed during 48 hours before vaccination and 15 days thereafter.

Culture water temperature during vaccination shall be equal to or slightly lower than the optimal culture temperature for sea bass (between 17 and 22 ºC).

Special precautions for safe use in the target species:
Do not vaccinate unhealthy animals or carriers of pathogenic microorganisms.

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.

To the user:
This veterinary medicinal product contains mineral oil. Accidental injection/self-injection may result in severe pain and swelling, particularly if injected into a joint or finger, and in rare cases could result in the loss of the affected finger if prompt medical attention is not given. If you are accidentally injected with this veterinary medicinal product, seek prompt medical advice even if only a very small amount is injected and take the package leaflet with you.
If pain persists for more than 12 hours after medical examination, seek medical advice again.

To the physician:
This veterinary medicinal product contains mineral oil. Even if small amounts have been injected, accidental injection with this product can cause intense swelling, which may, for example, result in ischaemic necrosis and even the loss of a digit. Expert, PROMPT, surgical attention is required and may necessitate early incision and irrigation of the injected area, especially where there is involvement of finger pulp or tendon.

Special precautions for the protection of the environment:
Not applicable.

Fertility:
The safety and efficacy have not been studied in breeders, therefore, the vaccination of breeders is not recommended.

Interactions with other medicinal products and other forms of interaction:
No information is available of 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:
Inactivated vaccine for which study of the safety of an overdose is not required.

Special restrictions for use and special conditions for use:
Not applicable.

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 (>1 animal / 10 animals treated):	Very slight adhesions close to the injection site.[1,2,3]
Common (1 to 10 animals / 100 animals treated):	Minor adhesions in the abdominal wall.[2,3]

[1]Unlikely to be noticed when evisceration
[2]Any observed adhesion disappears during the fattening period.
[3]Adverse events observed at necropsy 21 days after vaccination in laboratory safety studies.

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 using the contact details on this label, or via your national reporting system.

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

Dosage for each species, routes and method of administration

Administration by intraperitoneal injection in one dose of 0.1 ml/fish, when fish weight is approximately 15 g.

10. ADVICE ON CORRECT ADMINISTRATION

Advice on correct administration
Fish must be anaesthetised prior to vaccination.

The usage of vaccination guns with 23G needles is recommended. The needle should penetrate the abdominal wall minimum by 1 mm, to deposit the entire dose in the abdominal cavity.

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 to 8 °C)
Protect from light.
Do not freeze.

Do not use this veterinary medicinal product after the expiry date which is stated on the bottle after Exp. 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.

14. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

15. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Pack sizes

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 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 - Fax. +34 972 43 06 61
E-mail: hipra@hipra.com

<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.>

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: 10 hours.

21. BATCH NUMBER

Lot {number}