

[Version 8.1,01/2017]

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ICTHIOVAC-VR Concentrate for dip suspension/for injection for sea bass and turbot.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose contains:

Active substance:

Inactivated *Vibrio (Listonella) anguillarum* serotype O1 RPS(*) $\geq 60\%$

Inactivated *Vibrio (Listonella) anguillarum* serotype O2 α RPS(*) $\geq 60\%$

Inactivated *Vibrio (Listonella) anguillarum* serotype O2 β RPS(*) $\geq 60\%$

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

Excipients:

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Concentrate for dip suspension/for injection

Yellow-brownish suspension.

4. CLINICAL PARTICULARS

4.1 Target species

Sea bass (*Dicentrarchus labrax*)

Turbot (*Scophthalmus maxima*)

4.2 Indications for use, specifying the target species

For the active immunisation of sea bass and turbot to reduce mortality produced by *Vibrio (Listonella) anguillarum* (Serotypes O1, O2 α and O2 β).

Onset of immunity in turbot: 4 weeks after second dose at a water temperature between 16-18°C (448-504 degree days).

Onset of immunity in sea bass:

- Administration by immersion: 9 weeks after second dose at a water temperature between 19 – 21 °C (1197-1323 degree days).

- Intraperitoneal administration: 6 weeks after vaccination at a water temperature between 19 – 21 °C (798-882 degree days).

Duration of immunity: not established.

4.3 Contraindications

None.

4.4 Special warnings for each target species

Vaccinate healthy animals only .

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

Starvate 24h before vaccination.

Culture water temperature during vaccination shall be equal to or slightly lower than the optimal culture temperature for the species.

4.5 Special precautions for use

Special precautions for use in animals

It is necessary to maintain the oxygen level at saturation (by strong aeration) during the vaccination process, and monitor the oxygen level in the vaccinal suspension.

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.

4.6 Adverse reactions (frequency and seriousness)

Not described.

4.7 Use during pregnancy, lactation or lay

Do not use in breeders.

4.8 Interaction 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.

4.9 Amounts to be administered and administration route

Administration route: intraperitoneal and dipping.

Recommended vaccination scheme:

Turbot: vaccination by short dipping or prolonged dipping . Vaccinate for the first time when fish weight is between 0.5 g and 2 g. Administer a second dose after 4 weeks.

Sea bass:

- Vaccination by short dipping or prolonged dipping. Vaccinate for the first time when fish weight is between 0.5 g and 2 g. Administer a second dose after 6 weeks.
- Administration by intraperitoneal injection in one dose of 0.1 ml, when fish weight is at least 15 g.

Preparation and method of administration:

Shake well before use.

Vaccination by short dipping: Prepare a 1:10 (vaccine: water) dilution of the vaccine. Introduce in each 60-second immersion up to 0.5 Kg of fish per litre of diluted vaccine. The diluted vaccine can be reused for up to a maximum of 100 kg of fish per litre of vaccine.

Vaccination by prolonged dipping: 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. Thereafter the original water volume of the tank and its recirculation will be restored. Do not vaccinate more than 100 kg of fish per litre of vaccine.

Intraperitoneal injection: Fish must be anaesthetised prior to vaccination by using an authorized anesthetic for fish.

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.

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

No clinical signs have been observed after the administration of a 2-fold vaccine dose.

4.11 Withdrawal period(s)

Zero degree days.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Immunologicals for pisces. Turbot and others.

ATCvet code: QI10X, QI10D.

To stimulate active immunity against Vibriosis caused by *Vibrio (Listonella) anguillarum* in turbot and sea bass.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tryptic soy broth
Sodium chloride
Water for injections

6.2 Major incompatibilities

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

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.

6.4 Special precautions for storage

Store and transport refrigerated (2 to 8 °C).

Do not freeze.

Protect from light.

6.5 Nature and composition of immediate packaging

Package size: 1000 ml bottle.

The container-closure system consists of 1000 ml polypropylene bottles, chlorobutyl stoppers classified as Type I 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 products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Laboratorios Hipra, S.A.
Avda. la Selva, 135
17170-Amer (Girona) Spain

8. MARKETING AUTHORISATION NUMBER(S)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

10. DATE OF REVISION OF THE TEXT

PROHIBITION OF SALE, SUPPLY AND/OR USE

Conditions of dispensing: **subject to veterinary prescription.**

Conditions of administration: **subject to control or supervision of the veterinary surgeon.**

ANNEX III
LABELLING AND PACKAGE LEAFLET

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-VR Concentrate for dip suspension/for injection for sea bass and turbot.

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

Each dose contains:

Active substances:

Inactivated *Vibrio (Listonella) anguillarum* serotype O1 RPS(*) \geq 60%
Inactivated *Vibrio (Listonella) anguillarum* serotype O2 α RPS(*) \geq 60%
Inactivated *Vibrio (Listonella) anguillarum* serotype O2 β RPS(*) \geq 60%

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

Yellow-brownish suspension.

4. Pharmaceutical form

Concentrate for dip suspension/for injection

5. Package size

1,000 ml

6. Indication(s)

For the active immunisation of sea bass and turbot to reduce mortality produced by *Vibrio (Listonella) anguillarum* (Serotypes O1, O2 α and O2 β)

Onset of immunity in turbot: 4 weeks after second dose at a water temperature between 16-18°C (448-504 degree days).

Onset of immunity in sea bass:

- Administration by immersion: 9 weeks after second dose at a water temperature between 19 – 21 °C (1197-1323 degree days).
- Intraperitoneal administration: 6 weeks after vaccination at a water temperature between 19 – 21 °C (798-882 degree days).

Duration of immunity: not established.

7. Contraindications

None.

8. Adverse reactions

Not described.

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.

<h2>9. Target species</h2>

Sea bass (*Dicentrarchus labrax*)
Turbot (*Scophthalmus maxima*)

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

Administration route: intraperitoneal and dipping.

Recommended vaccination scheme:

Turbot: vaccination by short dipping or prolonged dipping. Vaccinate for the first time when fish weight is between 0.5 g- 2 g. Administer a second dose after 4 weeks.

Sea bass:

- Vaccination by short dipping or prolonged dipping. Vaccinate for the first time when fish weight is between 0.5 g and 2 g. Administer a second dose after 6 weeks.
- Administration by intraperitoneal injection in one dose of 0.1 ml, when fish weight is at least 15 g.

11. Advice on correct administration

Shake well before use.

Vaccination by short dipping: Prepare a 1:10 (vaccine: water) dilution of the vaccine. Introduce in each 60-second immersion up to 0.5 Kg of fish per litre of diluted vaccine. The diluted vaccine can be reused for up to a maximum of 100 kg of fish per litre of vaccine.

Vaccination by prolonged dipping: 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. Thereafter the original water volume of the tank and its recirculation will be restored. Do not vaccinate more than 100 kg of fish per litre of vaccine.

Intraperitoneal injection: Fish must be anaesthetised prior to vaccination by using an authorized anesthetic for fish.

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.

12. Withdrawal period(s)

Withdrawal period: Zero degree days.

13. Special storage precautions

Store and transport refrigerated (2 to 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-leaflet after EXP {month/year}. The expiry date refers to the last day of that month.

14. Special warning(s)

Special warnings for each target species

Vaccinate healthy animals only .

Starvate 24h before vaccination.

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 the species.

Special precautions for use in animals:

It is necessary to maintain the oxygen level at saturation (by strong aeration) during the vaccination process, and monitor the oxygen level in the vaccinal suspension

Fertility: Do not use in breeders

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.

Interaction 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 (symptoms, emergency procedures, antidotes):

No clinical signs have been observed after the administration of a 2-fold vaccine dose.

Incompatibilities:

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

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 size: 1000 ml bottle.

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}

Shelf life after the first opening of the container: Once opened use immediately.

21. Marketing authorisation number(s)

22. Manufacturer’s batch number

Batch/Lot {number}