ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ICTHIOVAC-STR ESTREPTOCOCOSIS RODABALLO, Suspension for injection
(Spanish name)
ICTHIOVAC-STR STREPTOCOCCOSE TURBOT, Suspension for injection
(French name)
ICTHIOVAC-STR ESTREPTOCOCOSES PREGADO, Suspension for injection
(Portuguese name)
ICTHIOVAC-STR STREPTOCOCCOSIS ΚΑΛΚΑΝΙ, Suspension for injection
(Greek name)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose (0.1 ml) contains:

Active substances:

Inactivated *Streptococcus parauberis,* strain RA-99.1	RPS ≥ 75%
Inactivated *Streptococcus parauberis*, strain AZ-12.1	RPS ≥ 75%

RPS: relative percentage of survival in turbot after laboratory challenge by intraperitoneal route.

Excipients:

Qualitative composition of excipients and other constituents
Sodium chloride
Trypic Soy Broth
Yeast extract
Water for injection

Yellowish suspension.

3. CLINICAL INFORMATION

3.1 Target species

Turbot (*Scophthalmus maximus*)

3.2 Indications for use for each target species

Active immunisation of turbots to reduce mortality associated with the infection by *Streptococcus parauberis*.
Onset of immunity: 4 weeks (water between 14 and 18ºC).
Duration of immunity: 2 years in normal production conditions.

3.3 Contraindications

None.

3.4 Special warnings

Vaccinate healthy animals only.

Fish should not be put under stress for the 4-5 days prior to vaccination and for the 4 weeks following vaccination.

The temperature of the water should be between 14 and 18ºC.

Water culture temperature for vaccination should be kept at the same or slightly lower temperature than the optimal one for the growth of the species.

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:

In case of accidental self-injection seek medical advice immediately and show the package leaflet or the label to the physician.

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 the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Fertility:
The safety of the vaccine has not been studied in breeding fish, therefore it is recommended not to vaccinate breeding fish.

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

Inoculate 0.1 ml/fish by intraperitoneal use.
The vaccine will be administered in the centre of the abdominal arc and in a postero-anterior direction.
Shake before use.

Recommended vaccination programme:
Turbot: one vaccination from 30 to 70g.

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

A two fold overdose showed no adverse events.

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

3.12 Withdrawal periods

Zero degree days.

4. IMMUNOLOGICAL INFORMATION

4.1 ATCvet code: QI10D

To stimulate an active immunity against *Streptococcus parauberis* in turbot.

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.

5.3 Special precautions for storage

Store and transport refrigerated (2ºC – 8ºC).
Protected from light.
Do not freeze.

5.4 Nature and composition of immediate packaging

The container consists of 500 ml polyethylene bottles, rubber stoppers and aluminium caps.

Package size:
500 ml bottle.

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)

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: {DD/MM/YYYY}

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

{DD/MM/YYYY}

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

A. LABELLING

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

500 ml (5.000 doses)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ICTHIOVAC-STR ESTREPTOCOCOSIS RODABALLO, Suspension for injection
(Spanish name)
ICTHIOVAC-STR STREPTOCOCCOSE TURBOT, Suspension for injection
(French name)
ICTHIOVAC-STR ESTREPTOCOCOSES PREGADO, Suspension for injection
(Portuguese name)
ICTHIOVAC-STR STREPTOCOCCOSIS ΚΑΛΚΑΝΙ, Suspension for injection
(Greek name)

2. STATEMENT OF ACTIVE SUBSTANCES

Each dose (0.1 ml) contains:

Inactivated *Streptococcus parauberis*, strain RA-99.1	RPS ≥ 75%
Inactivated *Streptococcus parauberis*, strain AZ-12.1	RPS ≥ 75%

RPS: relative percentage of survival in turbot after laboratory challenge by intraperitoneal route.

3. PACKAGE SIZE

500 ml

4. TARGET SPECIES

Turbot (*Scophthalmus maximus*)

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Intraperitoneal use.

7. WITHDRAWAL PERIODS

Withdrawal period: Zero degree days.

8. EXPIRY DATE

Exp. {mm/yyyy}
Once opened, use immediately.

9. SPECIAL STORAGE PRECAUTIONS

Store and transport refrigerated.
Protected from light.
Do not freeze.

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

11. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

12. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

13. MARKETING AUTHORISATION NUMBERS

LABORATORIOS HIPRA, S.A.

14. NAME OF THE MARKETING AUTHORISATION HOLDER

15. BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

ICTHIOVAC-STR ESTREPTOCOCOSIS RODABALLO, Suspension for injection
(Spanish name)
ICTHIOVAC-STR STREPTOCOCCOSE TURBOT, Suspension for injection
(French name)
ICTHIOVAC-STR ESTREPTOCOCOSES PREGADO, Suspension for injection
(Portuguese name)
ICTHIOVAC-STR STREPTOCOCCOSIS ΚΑΛΚΑΝΙ, Suspension for injection
(Greek name)

2. Composition

Each dose (0.1 ml) contains:

Active substances:

Inactivated *Streptococcus parauberis*, strain RA-99.1	RPS ≥ 75%
Inactivated *Streptococcus parauberis*, strain AZ-12.1	RPS ≥ 75%

RPS: relative percentage of survival in turbot after laboratory challenge by intraperitoneal route.

Yellowish suspension.

3. Target species

Turbot (*Scophthalmus maximus*)

4. Indications for use

Active immunisation of turbots to reduce mortality associated with the infection by *Streptococcus parauberis*.
Onset of immunity: 4 weeks (water between 14 and 18ºC).
Duration of immunity: 2 years in normal production conditions.

5. Contraindications

None.

6. Special warnings

Special warnings:
Vaccinate healthy animals only.

Fish should not be put under stress for the 4-5 days prior to vaccination and for the 4 weeks following vaccination.

The temperature of the water should be between 14 and 18ºC.

Water culture temperature for vaccination should be kept at the same or slightly lower temperature than the optimal one for the growth of the species.

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:
In case of accidental self-injection seek medical advice immediately and show the package leaflet or the label to the physician.

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

Fertility:
The safety of the vaccine has not been studied in breeding fish, therefore it is recommended not to vaccinate breeding fish.

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:
A two fold overdose showed no adverse events.

Special restrictions for use and special conditions for use:

Major incompatibilities:
Do not mix with any other veterinary medicinal product.

7. 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 package leaflet, 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 at the end of this leaflet, or via your national reporting system: {national system details}.

8. Dosage for each species, routes and method of administration

Inoculate 0.1 ml/fish by intraperitoneal use. The vaccine will be administered in the centre of the abdominal arc and in a postero-anterior direction.

Recommended vaccination programme:
Turbot: one vaccination from 30 to 70g.

9. Advice on correct administration

Shake before use.

10. Withdrawal periods

Zero degree-days.

11. Special storage precautions

Keep out of the sight and reach of children.
Store and transport refrigerated (2ºC – 8ºC).
Protect from light.
Do not freeze.
Shelf life after first opening the immediate packaging: use immediately.
Do not use this veterinary medicinal product after the expiry date which is stated on the label after Exp. The expiry date refers to the last day of that month.

12. 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.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Marketing authorisation number:

Pack sizes:
500 ml bottles

15. Date on which the package leaflet was last revised

{DD/MM/YYYY}

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

16. 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.