

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ICTHIOVAC-STR ESTREPTOCOCOSIS RODABALLO (Spanish name).

ICTHIOVAC-STR STREPTOCOCCOSE TURBOT (French name)

ICTHIOVAC-STR ESTREPTOCOCOSSES PREGADO (Portuguese name)

ICTHIOVAC-STR STREPTOCOCCOSIS KALKANI (Greek name)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Composition per dose (0.1 ml):

Active substance:

Inactivated *Streptococcus parauberis*, strain RA-99.1..... RPS \geq 75%

Inactivated *Streptococcus parauberis*, strain AZ-12.1..... RPS \geq 75%

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

3. PHARMACEUTICAL FORM

Suspension for injection

4. CLINICAL PARTICULARS

4.1 Target species

Species: Turbot (*Scophthalmus maximus/Psetta maxima*)

Size: 30 to 70g

4.2 Indications for use, specifying the target species

Active immunisation of turbot to reduce mortality associated with the infection by *Streptococcus parauberis*.

Onset of immunity: 4 weeks (water between +14 and +18°C).

Duration of immunity: 2 years in normal production conditions.

4.3 Contraindications

See section 4.7

Do not vaccinate diseased fish or those which are carriers of any pathogenic microorganism.

4.4 Special warnings for each target species

None

4.5 Special precautions for use

Special precautions for use in animals

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 +18°C. 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 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)

None has been described

4.7 Use during pregnancy, lactation or lay

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

4.8 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.

4.9 Amounts to be administered and administration route

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.

The temperature of the water should be between +14 and +18 °C

Shake before use.

Recommended vaccination programme:

Turbot: one vaccination from 30 to 70g

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

A two fold overdose showed no adverse effects.

4.11 Withdrawal period(s)

0 degrees-day.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Immunological for pisces, turbot

ATC vet code: QI10D

The vaccine ICTHIOVAC-STR ESTREPTOCOCOSIS RODABALLO stimulates an active immunity against *Streptococcus parauberis*.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium chloride
Tryptic Soy Broth
Yeast extract
Water for injection

6.2 Incompatibilities

Do not mix with any other veterinary medicinal product.

6.3 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 24 months.
Shelf-life after first opening the immediate packaging: use immediately.

6.4. Special precautions for storage

Store between +2°C and +8°C, protected from light. Do not freeze.

6.5 Nature and composition of immediate packaging

The container consists of 500 ml polyethylene bottles, rubber stoppers 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
1770- Amer (Girona) Spain
Tel (972) 430660- Fax (972) 430661

8. MARKETING AUTHORISATION NUMBER

Spain: 1465 ESP
Greece:
France:
Portugal:

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorization: 29/06/2005

10 DATE OF REVISION OF THE TEXT

PROHIBITION OF SALE, SUPPLY AND/OR USE

For animal treatment only – to be supplied only on veterinary prescription

LABELLING

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE (LABELLING)

500 ml (5,000 doses)

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ICTHIOVAC-STR ESTREPTOCOCOSIS PREGADO (Portuguese name)
ICTHIOVAC-STR STREPTOCOCCOSIS KALKANI (Greek name)

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Composition per dose (0.1 ml):

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

(RPS : relative percentage of survival in turbot after laboratory challenge by IP route.)

3. PHARMACEUTICAL FORM

Suspension for injection.

4. PACKAGE SIZE

500 ml (5,000 doses)

5. TARGET SPECIES

Species: Turbot (*Scophthalmus maximus* / *Psetta maxima*).
Size: 30 to 70 g.

6. INDICATION(S)

Active immunization of turbot to reduce mortality associated with the infection by *Streptococcus parauberis*.

7. METHOD AND ROUTE(S) 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.

8. WITHDRAWAL PERIOD

0 degrees-day.

9. SPECIAL WARNING(S), IF NECESSARY

- Shake before use.
- Do not vaccinate diseased fish or those which are carriers of any pathogenic microorganism.
- Fish should not be put under stress for the 4-5 days prior to vaccination and for the 4 weeks following vaccination.
- Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Once opened, use immediately.

11. SPECIAL STORAGE CONDITIONS

Store between +2 and +8 °C, protected from light. Do not freeze.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

13. 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.

14. THE WORDS “KEEP OUT OF THE REACH AND SIGHT OF CHILDREN”

Keep out of the reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

LABORATORIOS HIPRA, S.A.
Avda. la Selva, 135
17170 - AMER (Girona) Spain
Tel. (972) 430660

16. MARKETING AUTHORISATION NUMBER(S)
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17. MANUFACTURER'S BATCH NUMBER
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Batch {number}

PACKAGE LEAFLET

ICTHIOVAC-STR ESTREPTOCOCOSIS RODABALLO (Spanish name).
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ICTHIOVAC-STR STREPTOCOCCOSIS KALKANI (Greek name)

Inactivated vaccine against Streptococcosis in Turbot, injectable suspension

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

LABORATORIOS HIPRA, S.A.
Avda. la Selva, 135
17170 - AMER (Girona) Spain
Tel. (972) 430660

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

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3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Composition per dose (0.1 ml):

Inactivated *Streptococcus parauberis*, strain RA-99.1 RPS \geq 75%
Inactivated *Streptococcus parauberis*, strain AZ-12.1 RPS \geq 75%
(RPS : relative percentage of survival in turbot after laboratory challenge by IP route.)

4. INDICATION(S)

Active immunization of turbot to reduce mortality associated with the infection by *Streptococcus parauberis*.

Onset of immunity: 4 weeks (water between +14 and +18°C).

Duration of immunity: 2 years in normal production conditions.

5. CONTRAINDICATIONS

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

Do not vaccinate diseased fish or those which are carriers of any pathogenic microorganism

6. ADVERSE REACTIONS

None has been described.

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Species: Turbot (*Scophthalmus maximus* / *Psetta maxima*).

Size: 30 to 70 g.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) 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.

The temperature of the water should be between +14 and +18 °C.
Shake before use.

Recommended vaccination programme:

Turbot: One vaccination from 30 to 70 g.

9. ADVICE ON CORRECT ADMINISTRATION

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 +18 °C. 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.

10. WITHDRAWAL PERIOD

0 degrees-day.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight of children.

Store between +2 and +8 °C, protected from light. Do not freeze.

Once opened, use immediately.

12. SPECIAL WARNINGS

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

Do not mix with any other veterinary medicinal product.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT 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.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

Marketing Authorisation Number:

For animal treatment only

To be supplied only on veterinary prescription.

Pack sizes:

500 ml bottles (5,000 doses)