

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ICTHIOVAC-LG LACTOCOCOSIS TRUCHA
Inactivated vaccine in emulsion for injection for trout.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One dose (0.1 ml) contains:

Active substance:

Lactococcus garvieae inactivated, strain TW-446.B3 RPS ≥ 75% (*)

Adjuvants:

Montanide ISA-763 A..... 63.6364 mg

(*) RPS: *Relative Percentage of Survival*

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Whitish homogeneous emulsion for injection.

4. CLINICAL PARTICULARS

4.1 Target species

Trout (*Oncorhynchus mykiss*).

4.2 Indications for use, specifying the target species

For active immunization of trouts to reduce mortality caused by infection by *Lactococcus garvieae*.

Onset of immunity: 420 degree-days.
Duration of immunity: 3600 degree-days.

4.3 Contraindications

Do not vaccinate if the water temperature is below 10°C.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

Do not vaccinate unhealthy animals or carriers of pathogenic microorganisms.
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 trout (between 10 and 15 °C).
Shake before use.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

To the user:

This 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 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 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.

4.6 Adverse reactions (frequency and seriousness)

None has been described.

4.7 Use during pregnancy or lactation

Not applicable.

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

Trout: from 20 g of body weight.

The vaccine is administered by intraperitoneal injection at a dose of 0.1 ml / fish.

Recommended vaccination programme:

One single administration at 20 g.

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

No adverse reactions have been observed after the administration of a double vaccine dose.

4.11 Withdrawal period

Zero degree days.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Immunologicals for pisces, Rainbow trout, Inactivated bacterial vaccines and antisera.

ATCvet code: QI10BC.

To stimulate active immunity against *Lactococcus garvieae*.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

- Montanide ISA-763 A
- Sodium chloride
- Potassium chloride
- Potassium dihydrogen phosphate
- Disodium phosphate dodecahydrate
- Water for injections.

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: 5 hours.

6.4. Special precautions for storage

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

Do not freeze.

6.5 Nature and composition of immediate packaging

500 ml High Density Polyethylene (HDPE) bottles closed with bromobutyl stoppers and aluminium caps.

Pack sizes:

Bottles of 500 ml.

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

Tel. +34 972 430660

Fax. +34 972 430661

E-mail: hipra@hipra.com

8. MARKETING AUTHORISATION NUMBER

1642 ESP

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

13/07/2005

10. DATE OF REVISION OF THE TEXT

07/05/2010

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.

The import, sale, supply and/or use of ICTHIOVAC-LG LACTOCOCOSIS TRUCHA is or may be prohibited in certain Member States on the whole or part of their territory pursuant to national animal health policy. Any person intending to import, sell, supply and/or use ICTHIOVAC-LG LACTOCOCOSIS TRUCHA must consult the relevant Member State's competent authority on the current vaccination policies prior to the import, sale, supply and/or use.

