

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

**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:

LABORATORIOS HIPRA, S.A.  
Avda. la Selva, 135  
17170 Amer (Girona)  
SPAIN

**2. NAME OF THE VETERINARY MEDICINAL PRODUCT**

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

**3. STATEMENT OF THE ACTIVE SUBSTANCES AND OTHER INGREDIENTS**

*Lactococcus garvieae* inactivated, strain TW-446.B3: RPS  $\geq$  75% (\*)  
Montanide ISA-763 A: 63.6364 mg

(\*) RPS: *Relative Percentage of Survival*

**4. INDICATIONS**

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.

**5. CONTRAINDICATIONS**

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

**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**

Trout (*Oncorhynchus mykiss*).

## **8. DOSAGE FOR EACH SPECIES, ROUTE AND METHOD OF ADMINISTRATION**

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.

## **9. ADVICE ON CORRECT ADMINISTRATION**

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.

## **10. WITHDRAWAL PERIOD**

Zero degree-days.

## **11. SPECIAL STORAGE PRECAUTIONS**

Keep out of the reach and sight of children.

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

Do not use after the expiry date stated on the label.

Shelf life after first opening the immediate packaging: 5 hours.

## **12. SPECIAL WARNING(S)**

Do not vaccinate unhealthy animals or carriers of pathogenic microorganisms.

### **Special precautions for use in animals**

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.

**Use during pregnancy or lactation**

Not applicable.

**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.

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

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

**Incompatibilities**

Do not mix with any other vaccine or veterinary medicinal product.

**13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT 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.

**14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED**

07<sup>th</sup> May 2010

**15. OTHER INFORMATION**

Marketing authorisation number: 1642 ESP

Pack sizes: Bottles of 500 ml.

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

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