

**PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE
{LABEL}**

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

One dose (0.1 ml) contains:

Active substance:

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

Adjuvants:

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

(*) RPS: Relative Percentage of Survival

3. PHARMACEUTICAL FORM

Whitish homogeneous emulsion for injection.

4. PACKAGE SIZE

500 ml

5. TARGET SPECIES

Trout (*Oncorhynchus mykiss*).

6. 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.

7. METHOD AND ROUTE 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.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Withdrawal period: Zero degree days.

9. SPECIAL WARNINGS

Special warnings:

Do not vaccinate unhealthy animals or carriers of pathogenic microorganisms.
Accidental shelf-injection is dangerous – read package leaflet before use.

10. EXPIRY DATE

EXP {month/yyyy}

Once opened, use within 5 hours.

11. SPECIAL STORAGE CONDITIONS

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

Do not freeze.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTED 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

16. MARKETING AUTHORISATION NUMBER(S)

1642 ESP

17. MANUFACTURER’S BATCH NUMBER

Batch{number}