ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ICTHIOVAC-LG LACTOCOCOSIS TRUCHA emulsion for injection for trout

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose (0.1 ml) contains:

Active substance:
Lactococcus garvieae inactivated, strain TW-446.B3 RPS ≥ 75% (*)
(*) RPS: Relative Percentage of Survival

Adjuvants:
Montanide ISA-763 A 63.6364 mg

Excipients:

Qualitative composition of excipients and other constituents
Sodium chloride
Potassium chloride
Potassium dihydrogen phosphate
Disodium phosphate dodecahydrate
Water for injections.

Whitish homogeneous emulsion.

3. CLINICAL INFORMATION

3.1 Target species

Trout (*Oncorhynchus mykiss)*.

3.2 Indications for use for each 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.

3.3 Contraindications

None.

3.4 Special warnings

Vaccinate healthy animals only.
Do not vaccinate if the water temperature is below 10 °C.
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 ºC).

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.

To the user:
This veterinary medicinal 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 veterinary medicinal 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 veterinary medicinal 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.

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

3.6 Adverse events

None know.

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 systemhttps://www.ema.europa.eu/documents/template-form/qrd-appendix-i-adverse-event-phv-mss-reporting-details_en.docx. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Not applicable.

3.8 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.

3.9 Administration routes and dosage

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.

Shake before use.

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

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

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 : QI10BB.

To stimulate active immunity against *Lactococcus garvieae.*

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: 5 hours.

5.3 Special precautions for storage

Store and transport refrigerated (2 °C – 8 °C).
Protect from light.
Do not freeze.

5.4 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.

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

Bottle of 500 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ICTHIOVAC-LG LACTOCOCOSIS TRUCHA emulsion for injection for trout

2. STATEMENT OF ACTIVE SUBSTANCES

Each dose (0.1 ml) contains:

Active substance:

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

(*) RPS: Relative Percentage of Survival

Adjuvants:

Montanide ISA-763 A 63.6364 mg

3. PACKAGE SIZE

500 ml

4. TARGET SPECIES

Trout (*Oncorhynchus mykiss)*.

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 within 5 hours.

9. SPECIAL STORAGE PRECAUTIONS

Store and transport refrigerated.
Protect 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. NAME OF THE MARKETING AUTHORISATION HOLDER

LABORATORIOS HIPRA, S.A.

14. MARKETING AUTHORISATION NUMBERS

15. BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

ICTHIOVAC-LG LACTOCOCOSIS TRUCHA emulsion for injection for trout

2. Composition

Each dose (0.1 ml) contains:

Active substance:
Lactococcus garvieae inactivated, strain TW-446.B3: RPS ≥ 75% (*)
(*) RPS: Relative Percentage of Survival

Adjuvants:
Montanide ISA-763 A 63.6364 mg

Whitish homogeneous emulsion.

3. Target species

Trout (*Oncorhynchus mykiss)*.

4. Indications for use

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

None.

6. Special warnings

Special warnings:
Vaccinate healthy animals only.
Do not vaccinate if the water temperature is below 10 °C.
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 ºC).

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.

To the user:
This veterinary medicinal 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 veterinary medicinal 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 veterinary medicinal 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.

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

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

Special restrictions for use and special conditions for use:

Major incompatibilities:
Do not mix with any other vaccine or 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

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.

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 (2 °C – 8 °C).
Protect from light.
Do not freeze.

Do not use this veterinary medicinal product after the expiry date which is stated on the label. The expiry date refers to the last day of that month.
Shelf life after first opening the immediate packaging: 5 hours.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

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.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Marketing authorisation number:

Pack sizes: Bottles of 500 ml.

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 430660

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.