ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ICTHIOVAC ERM concentrate for dip suspension for Atlantic salmon

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substances:

Yersinia ruckeri, serotype O1, biotype 1, strain 8363, inactivated	≥ 10.19 $\log_{10}$ BDC*
Yersinia ruckeri, serotype O2, biotype 1, strain 8365, inactivated	≥ 10.07 $\log_{10}$ BDC*
Yersinia ruckeri, serotype O1, biotype 2, strain 8302, inactivated	≥ 9.91 $\log_{10}$ BDC*

*BDC: bacterial DNA copies

Excipients:

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

Light brown suspension.

3. CLINICAL INFORMATION

3.1 Target species

Atlantic salmon (*Salmo salar*)

3.2 Indications for use for each target species

Active immunisation of Atlantic salmon fry to reduce mortality caused by serotype O1 (biotypes 1 and 2) and serotype O2 (biotype 1) of *Yersinia ruckeri* in freshwater.

Onset and duration of immunity after completion of the recommended vaccination scheme:

Onset of immunity: 294 degree days (3 weeks at 14 ± 1 ºC).
Duration of immunity: 2,129 degree days (5 months at 14 ± 1 ºC).

3.3 Contraindications

None.

3.4 Special warnings

Vaccinate healthy animals only.
Starve the fish for 48 hours before vaccination.
Vaccination at water temperature of 12-16 ºC is recommended.

3.5 Special precautions for use

Special precautions for safe use in the target species:
It is not recommended to vaccinate fish with signs of clinical disease.

It is necessary to maintain a strong aeration during the vaccination process and monitor on the oxygen level in the vaccine solution (maintaining the oxygen level at saturation).

Avoid any management and/or rearing procedures which may cause stress to the fish during 48 hours before vaccination and 7 days thereafter.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
In case of accidental spillage onto skin or contact with eyes, rinse immediately with plenty of water.

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

3.6 Adverse events

Atlantic salmon: None known.

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 system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Fertility
The safety of the veterinary medicinal product in future broodstock has not been established.

3.8 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.

3.9 Administration routes and dosage

Administration route: Dipping.

Shake the vaccine bottle well before use.

Vaccination scheme:
The vaccination scheme consists of two administrations. Administer the vaccine for the first time when fish weight is at least 3 g and for the second time when fish weight is at least 8 g.

Mix 1 litre of vaccine concentrate with 59 litres of water to obtain 60 litres of diluted vaccine.
Immerse in batches of up to 0.6 kg of fish per litre of diluted vaccine for a period of 60 seconds.
Immerse not more than 375 kg (first administration) or 600 kg (second administration) of fish per litre of vaccine (or 60 litres of diluted vaccine).

To reduce dilution of the vaccine solution, drain as much water as possible from each batch of fish (but not compromising animal welfare) before the fish are immersed in the vaccine solution.

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

No adverse events from causes attributable to the product have been observed after administration of a double concentration for twice the immersion time recommended.

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

Not applicable.

3.12 Withdrawal periods

Zero degree days.

4. IMMUNOLOGICAL INFORMATION

4.1 ATCvet code: QI10AB04

To stimulate active immunity in Atlantic salmon fry to reduce mortality caused by serotype O1 (biotypes 1 and 2) and serotype O2 (biotype 1) of *Yersinia ruckeri* in freshwater.

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: Use immediately.

5.3 Special precautions for storage

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

5.4 Nature and composition of immediate packaging

1,000 ml colourless polypropylene bottles closed with polymeric elastomer stoppers and aluminium caps.

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)

EU/2/24/330/001

8. DATE OF FIRST AUTHORISATION

23/01/2025

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

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 II

OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

None

ANNEX III

LABELLING AND PACKAGE LEAFLET

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE - <u>COMBINED LABEL AND PACKAGE LEAFLET</u>

BOTTLE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ICTHIOVAC ERM concentrate for dip suspension for Atlantic salmon

2. COMPOSITION

Active substances:

Yersinia ruckeri, serotype O1, biotype 1, strain 8363, inactivated	≥ 10.19 $\log_{10}$ BDC*/ml
Yersinia ruckeri, serotype O2, biotype 1, strain 8365, inactivated	≥ 10.07 $\log_{10}$ BDC*/ml
Yersinia ruckeri, serotype O1, biotype 2, strain 8302, inactivated	≥ 9.91 $\log_{10}$ BDC*/ml

*BDC: bacterial DNA copies

Light brown suspension.

3. PACKAGE SIZE

1,000 ml

4. TARGET SPECIES

Atlantic salmon (*Salmo salar*)

5. INDICATIONS FOR USE

Indications for use

Active immunisation of Atlantic salmon fry to reduce mortality caused by serotype O1 (biotypes 1 and 2) and serotype O2 (biotype 1) of *Yersinia ruckeri* in freshwater.

Onset and duration of immunity after completion of the recommended vaccination scheme: onset of 294 degree days (3 weeks at 14 ± 1 ºC) and duration of 2,129 degree days (5 months at 14 ± 1 ºC).

6. CONTRAINDICATIONS

Contraindications

None.

7. SPECIAL WARNINGS

Special warnings

<u>Special warnings:</u>

Vaccinate healthy animals only. Starve the fish for 48 hours before vaccination. Vaccination at water temperature of 12-16 ºC is recommended.

Special precautions for safe use in the target species:
It is not recommended to vaccinate fish with signs of clinical disease.
It is necessary to maintain a strong aeration during the vaccination process and monitor on the oxygen level in the vaccine solution (maintaining the oxygen level at saturation).
Avoid rearing procedures which may cause stress to the fish during 48 hours before vaccination and 7 days thereafter.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
In case of accidental spillage onto skin or contact with eyes, rinse immediately with plenty of water.

Fertility:
The safety of the veterinary medicinal product in future broodstock has not been established.

Interactions 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 events from causes attributable to the product have been observed after administration of a double concentration for twice the immersion time recommended.

Major incompatibilities:
Do not mix with any other veterinary medicinal product.

8. ADVERSE EVENTS

Adverse events

Atlantic salmon: 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 on this label, 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 on this label, or via your national reporting system {national system details}.

9. DOSAGE FOR EACH TARGET SPECIES, ROUTES AND METHOD OF ADMINISTRATION

Dosage for each species, routes and method of administration
Administer the veterinary medicinal product by immersion using a vaccination scheme consisting of two administrations. Administer the vaccine for the first time when fish weight is at least 3 g and for the second time when fish weight is at least 8 g.

Mix 1 litre of vaccine concentrate with 59 litres of water to obtain 60 litres of diluted vaccine. Immerse in batches of up to 0.6 kg of fish per litre of diluted vaccine for a period of 60 seconds. Immerse not more than 375 kg (first administration) or 600 kg (second administration) of fish per litre of vaccine (or 60 litres of diluted vaccine).

10. ADVICE ON CORRECT ADMINISTRATION

Advice on correct administration
Shake the vaccine bottle well before use.

To reduce dilution of the vaccine solution, drain as much water as possible from each batch of fish (but not compromising animal welfare) before the fish are immersed in the vaccine solution.

11. WITHDRAWAL PERIODS

Withdrawal periods
Zero degree days.

12. SPECIAL STORAGE PRECAUTIONS

Special storage precautions

Keep out of the sight and reach of children.

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

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

13. SPECIAL PRECAUTIONS FOR DISPOSAL

Special precautions for disposal

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 applicable national collection systems. These measures should help to protect the environment.

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

14. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Classification of veterinary medicinal products
Veterinary medicinal product subject to prescription.

15. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

EU/2/24/330/001

Pack sizes
1,000 ml

16. DATE ON WHICH THE LABEL WAS LAST REVISED

Date on which the label was last revised

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

17. CONTACT DETAILS

Contact details

Marketing authorisation holder, 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 43 06 60

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.

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18. OTHER INFORMATION

19. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

20. EXPIRY DATE

Exp {mm/yyyy}

Shelf life after first opening the immediate packaging: use immediately.

21. BATCH NUMBER

Lot {number}