SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

AquaVac ERM concentrate for dip suspension for Rainbow trout

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose contains:

Active substance:
Yersinia ruckeri, serotype O1, strain Hagerman, inactivated inducing RPS(*) ≥ 75%

*RPS: relative percentage of survival in Rainbow Trout

Excipients:

Qualitative composition of excipients and other constituents
Formaldehyde
Sodium chloride solution

Yellowish-brown suspension.

3. CLINICAL INFORMATION

3.1 Target species

Rainbow trout (*Oncorhynchus mykiss)*.

3.2 Indications for use for each target species

In Rainbow Trout of 2 grams weight or over: Active immunisation against Enteric Redmouth disease (ERM) to reduce mortality caused by the Hagerman Type I strain of *Yersinia ruckeri.*

Onset of immunity: 28 days at a water temperature of 12 ^{o}C (336 degree days are required for the development of full immunity). The time for development of protective immunity will depend on water temperature.

Duration of immunity: 78 days (shown under laboratory conditions).
Under field conditions, protection may be expected for at least 6 months. A booster vaccination administered 4 months after primary vaccination may induce a better level of protection.

3.3 Contraindications

None.

3.4 Special warnings

Vaccinate healthy animals only.

3.5 Special precautions for use

Special precautions for safe use in the target species:
During vaccination, the temperature of the diluted vaccine should not differ from the water temperature in the holding area by more than ± 5 °C.

Fish should be subjected to the minimum of manipulations such as sorting and transportation during the periods shortly before and after vaccination.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Personal protective equipment consisting of rubber gloves should be worn when handling the veterinary medicinal product.

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

3.6 Adverse events

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.
{< > to be adjusted nationally}

3.7 Use during pregnancy, lactation or lay

Fertility:
Do not administer to fish intended as broodstock or to broodstock.

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

The product is administered to Rainbow Trout of not less than 2 grams in weight by immersion for 30 seconds in vaccine diluted 1 in 10 with hatchery water. 1 litre of vaccine, diluted to 10 litres in total, is sufficient to vaccinate 100 kg of fish.
Fish may be vaccinated in batches. The size of each batch should be appropriate to the volume of diluted vaccine available and to the size of the fish. The diluted vaccine should be oxygenated, if necessary, between vaccinations of individual batches.

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

No adverse effects have been noted following a double dose of vaccine.

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 : QI10BB03.

To stimulate active immunity in Rainbow Trout against Enteric Redmouth disease caused by *Yersinia ruckeri.*

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 dilution according to directions: 5 hours.

5.3 Special precautions for storage

Store in a refrigerator (2 °C – 8 °C).
Do not freeze.
Protect from light.

5.4 Nature and composition of immediate packaging

High density polyethylene bottles, closed with a rubber stopper and sealed with an aluminium cap containing 1000 ml of vaccine.

Pack size:
1000 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>.
{< >to be adjusted nationally}

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

{Name} {to be completed nationally}

7. MARKETING AUTHORISATION NUMBER(S)

{to be completed nationally}

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: {DD/MM/YYYY}. {to be completed nationally}

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

{MM/YYYY} {to be completed nationally}

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).

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE*

Bottle (label)

** The label and leaflet are presented in a fold-out format. The label text of this section will appear twice in the packaging material ie. In the outermost face of the fold-out and the inner face in the closest contact of the bottle.*

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

AquaVac ERM Concentrate for dip suspension

2. STATEMENT OF ACTIVE SUBSTANCES

Each dose contains:

Yersinia ruckeri, serotype O1, strain Hagerman, inactivated ≥ 75% RPS*
*RPS: relative percentage of survival in Rainbow Trout

3. PACKAGE SIZE

1000 ml

4. TARGET SPECIES

Rainbow trout (*Oncorhynchus mykiss)*

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Immersion use.

7. WITHDRAWAL PERIODS

Withdrawal period: zero degree days.

8. EXPIRY DATE

Exp. {mm/yyyy}

Once diluted use within 5 hours.

9. SPECIAL STORAGE PRECAUTIONS

Store in a refrigerator.

Do not freeze.
Protect from light.

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

{Name or company name or logo name of the marketing authorisation holder}.
{to be completed nationally}

14. MARKETING AUTHORISATION NUMBERS

EU/2/00/000/000
{to be completed nationally}

15. BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

AquaVac ERM Concentrate for dip suspension for Rainbow Trout

2. Composition

Each dose contains:

Active substance:
Yersinia ruckeri, serotype O1, strain Hagerman, inactivated inducing ≥ 75% RPS*

*RPS: relative percentage of survival in Rainbow Trout

Yellowish-brown suspension.

3. Target species

Rainbow trout (*Oncorhynchus mykiss)*.

4. Indications for use

In Rainbow Trout of 2 grams weight or over: Active immunisation against Enteric Redmouth disease (ERM) to reduce mortality caused by the Hagerman Type I strain of *Yersinia ruckeri.*

Onset of immunity: 28 days at a water temperature of 12 °C (336 degree days are required for the development of full immunity). The time for development of protective immunity will depend on water temperature.

Duration of immunity: 78 days (shown under laboratory conditions).
Under field conditions, protection may be expected for at least 6 months. A booster vaccination administered 4 months after primary vaccination may induce a better level of protection.

5. Contraindications

None.

6. Special warnings

Special warnings:
Vaccinate healthy animals only.

Special precautions for safe use in the target species:
During vaccination, the temperature of the diluted vaccine should not differ from the water temperature in the holding area by more than ± 5 °C.

Fish should be subjected to the minimum of manipulations such as sorting and transportation during the periods shortly before and after vaccination.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Personal protective equipment consisting of rubber gloves should be worn when handling the veterinary medicinal product.

Fertility:
Do not administer to fish intended as broodstock or to broodstock.

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 effects have been noted following a double dose of vaccine.

Major incompatibilities:
Do not mix with any other 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}.
{< > to be adjusted nationally}

8. Dosage for each species, routes and method of administration

The product is administered to Rainbow Trout of not less than 2 grams in weight by immersion for 30 seconds in vaccine diluted 1 in 10 with hatchery water. 1 litre of vaccine, diluted to 10 litres in total, is sufficient to vaccinate 100 kg of fish.

9. Advice on correct administration

Fish may be vaccinated in batches. The size of each batch should be appropriate to the volume of diluted vaccine available and to the size of the fish. The diluted vaccine should be oxygenated, if necessary, between vaccinations of individual batches.

10. Withdrawal periods

Zero degree days.

11. Special storage precautions

Keep out of the sight and reach of children.
Store in a refrigerator (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. The expiry date refers to the last day of that month.

Shelf life after dilution according to directions: 5 hours.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater<or household waste>.
{< >to be adjusted nationally}

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.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Pack size:
1000 ml
{to be completed nationally}

15. Date on which the package leaflet was last revised

{MM/YYYY}{to be completed nationally}

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>:
{< > to be adjusted nationally}

Manufacturer responsible for batch release[1]: {to be adjusted nationally if included in the above}
Intervet UK, Ltd.
Walton Manor, Walton
Milton Keynes
Buckinghamshire, MK7 7AJ
United Kingdom

Merck Sharp & Dohme Animal Health S.L.
Poligono Industrial El Montalvo I
C/Zeppelin 6, Parcela 38,
37008 Carbajosa de La Sagrada (Salamanca)
Spain

<Local representatives <and contact details to report suspected adverse reactions>:>

{< > to be adjusted nationally}

<For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.>
{< > to be adjusted nationally}

17. Other information

For animal treatment only.

{to be completed nationally}

[1] The printed package leaflet will state the name and address of the manufacturer responsible for the release of the concerned batch only.