SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

AquaVac Relera concentrate for dip suspension or suspension for injection for rainbow trout

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1 ml of vaccine (concentrate) contains:

Active substances:
Yersinia ruckeri serotype O1, biotype 1, strain Hagerman, inactivated, inducing ≥ 75% RPS*
Yersinia ruckeri serotype O1, biotype 2 (EX5), strain SP/07/04, inactivated, inducing ≥ 75% RPS*

*RPS: relative percentage of survival in rainbow trout

Excipients:

Qualitative composition of excipients and other constituents
Formaldehyde
Sodium chloride
Water for injection

Suspension in brown aqueous liquid.

3. CLINICAL INFORMATION

3.1 Target species

Rainbow trout (*Oncorhynchus mykiss*).

3.2 Indications for use for each target species

Active immunisation against Enteric Redmouth disease (ERM) to reduce mortality caused by Hagerman type 1 and EX5 biotype strains of *Yersinia ruckeri*.

Immersion route:
Onset of immunity: 336 degree days (28 days at 12 °C) for Hagerman type 1 and for EX5 biotype.

Duration of immunity:
6 months (205 days at 12 °C) for the Hagerman type 1.
4 months (133 days at 12 °C) for the EX5 biotype.

Please note that the level of protection against the EX5 biotype wanes during the indicated period.

Intraperitoneal route (only for booster vaccination):
Duration of immunity: immunity has not been studied beyond 28 days (336 degree days).

3.3 Contraindications

None.

3.4 Special warnings

Vaccinate healthy animals only.
Do not vaccinate if the water temperature is below 12 °C.
The minimum weights for fish before vaccination must be respected (see section 3.9 of the SPC).

3.5 Special precautions for use

Special precautions for safe use in the target species:
Avoid stress at the time of the handling of fish, as well as temperature variations, in particular between the vaccine suspension and the water of the holding area.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Personal protective equipment consisting of guarded needles or needle protectors should be worn when handling the veterinary medicinal product.
In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

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

3.6 Adverse events

Rainbow trout (*Oncorhynchus mykiss*):

Very common (>1 animal / 10 animals treated):	Adhesion in fish[1].

[1] Very slight (Speilberg score 1) induced by injection administration at the site of injection, which may persist for 7 weeks but are normally no longer observed 3 months after injection.

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:
Do not administer to broodstock or fish intended as 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

Primary vaccination should be by the immersion route only. In the event that a booster vaccination is required to extend the duration of immunity for a further 28 days then the intraperitoneal route should be used.

When administering by immersion, dilute the contents immediately after opening the container, and use diluted vaccine immediately.
The development of protective immunity is dependent on the water temperature.
Shake the bottle before use.

Primary vaccination by immersion (Fish of at least 5 g)
Dilute the contents of the bottle (1 litre) in 9 litres of hatchery water, clean and suitably oxygenated.
Place the fish into batches and immerse for 30 seconds in the diluted vaccine.

A litre of vaccine (making 10 litres of diluted vaccine) allows the vaccination of a maximum of 100 kg of fish.

Booster vaccination by intraperitoneal injection (Fish of at least 12 g)
The vaccine must be administered using a multi-dose injection applicator incorporating a mechanism to prevent flush-back. This applies equally to hand-held and automatic systems.
The product is administered by intraperitoneal injection in the ventral area, just anterior to the pelvic fins. The dose is 0.1 ml per fish.
The fish should be anaesthetised prior to vaccination.

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

No adverse effects have been noted following a double dose of vaccine by immersion or intraperitoneal injection other than those mentioned in section 3.6.

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.

The vaccine induces active immunity against Enteric Redmouth disease caused by *Yersinia ruckeri*, Hagerman type 1 strain and the EX5 biotype.

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 within 5 hours.

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

The product is supplied in 1000 ml crimp-sealed bottles: high-density polyethylene bottles, red bromobutyl stoppers, aluminium cap.

Pack size:
1000 ml (10000 doses)

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.

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

Intervet International B.V.

7. MARKETING AUTHORISATION NUMBERS

Vm 06376/5035
Vm 06376/3037

8. DATE OF FIRST AUTHORISATION

15 May 2009

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

March 2025

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).

Approved 12 March 2025

Gavin Hall