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.

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.

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 Ireland Limited

7. MARKETING AUTHORISATION NUMBER(S)

VPA10996/214/001

8. DATE OF FIRST AUTHORISATION

22/10/2010

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

01/08/2024

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).