

SUMMARY OF PRODUCT CHARACTERISTICS

- 1 NAME OF THE VETERINARY MEDICINAL PRODUCT**
AquaVac ERM
- 2 QUALITATIVE AND QUANTITATIVE COMPOSITION**
Active ingredient
Inactivated cells of *Yersinia ruckeri*
(Hagerman type I strain) RPS(*) ≥ 75% after vaccination
Other constituents
Formaldehyde not greater than 0.5 mg/mL
*RPS : relative percentage of survival in Rainbow Trout
- 3 PHARMACEUTICAL FORM**
Concentrate for dip suspension
- 4 IMMUNOLOGICAL PROPERTIES**
To stimulate active immunity in Rainbow Trout against Enteric Redmouth disease caused by *Yersinia ruckeri*.
ATC Vet Code QI10BB03
- 5 CLINICAL PARTICULARS**
- 5.1 TARGET SPECIES
Rainbow trout (*Onchorynchus mykiss*)
- 5.2 INDICATIONS FOR USE
In Rainbow Trout of 2 grams weight or over: Active immunization against Enteric Redmouth disease (ERM) to reduce mortality caused by the Hagerman Type I strain of *Yersinia ruckeri*.
336 degree days are required for the development of full immunity (28 days at a water temperature of 12°C). The time for development of protective immunity will depend on water temperature.
A duration of immunity of 78 days has been 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.
- 5.3 CONTRAINDICATIONS
None
- 5.4 UNDESIRABLE EFFECTS
None
- 5.5 SPECIAL PRECAUTIONS FOR USE

During vaccination, the temperature of the diluted vaccine should not differ from the water temperature in the holding area by more than $\pm 5^{\circ}\text{C}$.

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

5.6 USE DURING PREGNANCY AND LACTATION

Do not administer to fish intended as broodstock or to broodstock

5.7 INTERACTION WITH OTHER VACCINES AND MEDICINAL PRODUCTS WHEN ADMINISTERED IN COMBINATION WITH THE PRODUCT

Only limited information is available on the safety and efficacy from the concurrent use of this vaccine with any other vaccines or medicaments. It is therefore recommended that no other vaccines should be administered within 168 degree days (14 days at 12°C) before or after vaccination with AquaVac ERM.

5.8 POSOLOGY 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. 1L of vaccine, diluted to 10L in total, is sufficient to vaccinate 100kg 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.

5.9 OVER-DOSE

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

5.10 SPECIAL WARNINGS FOR EACH TARGET SPECIES

Only vaccinate healthy fish.

5.11 WITHDRAWAL PERIODS

Zero days

5.12 SPECIAL PRECAUTIONS TO BE TAKEN BY THE PERSONS ADMINISTERING THE MEDICINAL PRODUCT TO ANIMALS

Personal protective equipment consisting of rubber gloves should be worn during all vaccination operations.

6 PHARMACEUTICAL PARTICULARS

6.1 MAJOR INCOMPATIBILITIES

Do not mix with any other vaccine/immunological product.

6.2 SHELF LIFE

24 months.

After opening, dilute the contents immediately, and do not store; use contents immediately.

6.3 SPECIAL PRECAUTIONS FOR STORAGE

Store at $+2^{\circ}\text{C}$ to $+8^{\circ}\text{C}$.

Protect from light

- 6.4 Do not freeze
NATURE AND CONTENTS OF CONTAINER

Nature of primary packaging

high-density polyethylene bottles
red bromobutyl stoppers
Aluminium cap

Packages intended for sales

1L bottle

- 6.5 SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Any unused veterinary medicinal product or waste materials from such veterinary medicinal products should be disposed of in accordance with national requirements.

- 7 **NAME OR CORPORATE NAME AND ADDRESS OR REGISTERED PLACE OF BUSINESS OF THE HOLDER OF THE MARKETING AUTHORISATION**

Schering-Plough Limited, Schering-Plough House, Shire Park, Welwyn Garden City, Hertfordshire AL7 1TW, UK

Additional information

Prohibition of sale, supply or use	None
Marketing authorisation number:	Vm 00201/4193
Date of authorisation:	TBD
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