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

Active substance :
Inactivated cells of *Yersinia ruckeri*
(Hagerman type I strain) RPS(*) ≥ 75% after vaccination

Excipient:
Formaldehyde: ≤ 0.5 mg/ml

*RPS : relative percentage of survival in Rainbow Trout

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Concentrate for dip suspension.

4 CLINICAL PARTICULARS

4.1 Target Species

Rainbow trout (*Oncorhynchus mykiss).*

4.2 Indications for use, specifying the target species

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.

4.3 Contraindications

None.

4.4 Special warnings for each target species

Only vaccinate healthy fish.

4.5 Special precautions for use

Special precautions for use in animals

During vaccination, the temperature of the diluted vaccine should not differ from the water temperature in the holding area by more than ± 5^{o}C.
Fish should be subject 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 during all vaccination operations.

4.6 Adverse reactions (frequency and seriousness)

None.

4.7 Use during pregnancy, lactation or lay

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

4.8 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.

4.9 Amounts to be administered and administration route

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 litre 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.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

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

4.11 Withdrawal Period(s)

Zero days.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

To stimulate active immunity in Rainbow Trout against Enteric Redmouth disease caused by *Yersinia ruckeri.*
ATC Vet Code QI10BB03.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Formaldehyde
Sodium chloride solution

6.2 Incompatibilities

Do not mix with any other veterinary medicinal product.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf-life after dilution according to directions: 5 hours.

6.4 Special precautions for storage

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

6.5 Nature and composition of immediate packaging

High density polyethylene bottles, closed with a rubber stopper and sealed with an aluminium cap containing 1 litre of vaccine.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

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

7 MARKETING AUTHORISATION HOLDER

Intervet Ireland Ltd.
Magna Drive,
Magna Business Park,
Citywest Road,
Dublin 24

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10996/214/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

3rd August 2009

10 DATE OF REVISION OF THE TEXT