Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

AquaVac ERM Oral.
Oral emulsion for rainbow trout.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance

Inactivated cells of *Yersinia ruckeri* (Hagerman type I strain): RPS*> 60% after vaccination.

(*RPS: relative percentage survival in Rainbow trout).

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Oral Emulsion.

4 CLINICAL PARTICULARS

4.1 Target Species

Rainbow trout (*Oncorhynchus mykiss).*

4.2 Indications for use, specifying the target species

Active immunization of rainbow trout, 26g and above against Enteric Redmouth disease (ERM) to reduce mortality caused by the Hagerman Type I strain (serotype 01) of *Yersinia ruckeri*. The vaccine is indicated for use in fish that have been vaccinated by immersion with AquaVac ERM within the previous 4 to 6 months.
The time to achieve full effect of the vaccination will depend on water temperature.
In fish vaccinated by immersion 4.5 months previous to oral vaccination, vaccine efficacy was demonstrated under field conditions at water temperatures of 10°C, 21 days (210 degree days) after completion of the vaccine feeding protocol and protection was observed for the 3 month duration of the field trial.

4.3 Contraindications

None.

4.4 Special warnings for each target species

Do not vaccinate fish at water temperatures below 5^{o}C.
Only vaccinate healthy fish.

4.5 Special precautions for use

Special precautions for use in animals

The safety and efficacy of AquaVac ERM Oral has only been demonstrated when the product was used after fish had been vaccinated with AquaVac ERM within the previous 4 to 6 months.

Do not re-vaccinate fish previously vaccinated with AquaVac ERM Oral.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

Wear rubber gloves when preparing and handling vaccine treated pellets. Protection against particle and droplet inhalation e.g. a dust mask, should be worn when spraying and mixing vaccine onto feed pellets.

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 orally, to fish that have received vaccination with AquaVac ERM immersion vaccine 4-6 months previously.

Vaccination is administered to fish of not less than 26 g weight in a 10-day feeding program, in which feed pellets treated with vaccine are administered according to the following protocol:

Day 1-5	0.01 ml per fish per day
Day 6-10	No vaccine feed
Day 11-15	0.01 ml per fish per day
Total	0.1 ml per fish

The precise bacterial dose taken up by individual fish cannot be calculated.

Preparation of vaccine-coated feed pellets.

The vaccine-coated feed is prepared as follows:

The vaccine is kept at room temperature (20°C) for 1 hour before use to allow the vaccine to become less viscous. If any separation occurs, the bottle is shaken vigorously until the separated layers are completely dispersed. The feed pellets are turned in a mixer, e.g. concrete mixer and the vaccine is slowly poured or sprayed directly onto the pellets. If a sprayer is used, it should be set to deliver a coarse spray without risk of aerosol particle generation and the spray container must be completely emptied during the mixing operation. The pellets are mixed for at least 2 minutes after all the vaccine has been added. The prepared feed is kept for 1 hour before feeding to allow the vaccine to impregnate the pellets completely.

The vaccine can be mixed with all or one part of the daily ration of feed.

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 degree days.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

To stimulate active immunity against Enteric Redmouth disease (ERM) to reduce mortality caused by the Hagerman Type I strain (Serotype 01) of *Yersinia ruckeri.*
ATC Vet Code QI10BB03

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Formaldehyde
Sodium chloride solution
Fish Oil
Lecithin

6.2 Incompatibilities

Do not mix with any other veterinary medicinal product.

6.3 Shelf-life

Shelf life of the veterinary medicianl product as packaged for sale: 2 years
Shelf lfie after first opening the immediate packaging: immediate use
Shelf life after incorporation into pellet feed: 19 days

6.4 Special precautions for storage

Store and transport refrigerated (2°C to 8°C).
Do not freeze.
Protect from light.
Vaccine treated feed should be stored at 20°C ± 5°C in a dry, dark place.

6.5 Nature and composition of immediate packaging

1000ml (10 000 dose) high density polyethylene bottles sealed with a rubber stopper and aluminium crimp seal.

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 product should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Intervet Ireland Limited
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Magna Business Park
Citywest Road
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8 MARKETING AUTHORISATION NUMBER(S)

VPA 10996/218/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

28th February 2011

10 DATE OF REVISION OF THE TEXT

June 2011