

## **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**

Each dose contains:

#### **Active substance:**

*Yersinia ruckeri*, serotype O1, strain Hagerman, inactivated inducing RPS(\*)  $\geq 75\%$

\*RPS: relative percentage of survival in Rainbow Trout

#### **Excipients:**

<b>Qualitative composition of excipients and other constituents</b>
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 °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  $\pm 5^{\circ}\text{C}$ .

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.

Other precautions:

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 product 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**

MSD Animal Health UK Limited

**7. MARKETING AUTHORISATION NUMBER**

Vm 01708/5124

**8. DATE OF FIRST AUTHORISATION**

03 August 2004

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

August 2024

**10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT**

Veterinary medicinal product subject to prescription.

Find more product information by searching for the 'Product Information Database' on [www.gov.uk](http://www.gov.uk).

*Gavin Hall*  
Approved: 12 December 2024