

## **B. PACKAGE LEAFLET**

**PACKAGE LEAFLET<sup>1</sup>:  
AquaVac ERM**

**1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER  
AND OF THE MANUFACTURING AUTHORISATION HOLDER  
RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT**

Marketing authorisation holder:

MSD Animal Health UK Ltd.  
Walton Manor  
Walton  
Milton Keynes  
Buckinghamshire  
MK7 7AJ

Manufacturer responsible for batch release:<sup>2</sup>

MSD Animal Health UK Ltd.  
Walton Manor, Walton  
Milton Keynes  
Buckinghamshire, MK7 7AJ  
United Kingdom

Merck Sharp & Dohme Animal Health S.L.  
Poligono Industrial El Montalvo I  
C/Zepelin 6, Parcela 38,  
37008 Carbajosa de La Sagrada (Salamanca)  
Spain

**2. NAME OF THE VETERINARY MEDICINAL PRODUCT**

AquaVac ERM Concentrate for dip suspension for Rainbow Trout

**3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER  
INGREDIENT(S)**

Inactivated cells of *Yersinia ruckeri*  $\geq$  75% RPS\*  
(Hagerman type I strain)

\*RPS: relative percentage of survival in Rainbow Trout

Formaldehyde  $\leq$  0.5 mg/ml

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<sup>1</sup> This text will form the label for the product. There is no separate leaflet for this product. The text numbering is taken from the template for the package leaflet, and under 15 Other Information is given the additional information required by the label template.

<sup>2</sup> The printed package leaflet will state the name and address of the manufacturer responsible for the release of the concerned batch only.

#### **4. INDICATION(S)**

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. CONTRAINDICATIONS**

None.

#### **6. ADVERSE REACTIONS**

None.

#### **7. TARGET SPECIES**

Rainbow trout (*Oncorhynchus mykiss*)

#### **8. DOSAGE FOR EACH SPECIES, ROUTE(S) 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. 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.

#### **9. ADVICE ON CORRECT ADMINISTRATION**

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

