B. PACKAGE LEAFLET

PACKAGE LEAFLET1: AquaVac ERM

NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER 1. 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: 2 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/Zeppelin 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 ≥ 75% RPS* (Hagerman type I strain) *RPS: relative percentage of survival in Rainbow Trout

Formaldehyde

≤ 0.5 mg/ml

¹ 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.

² 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°C. Fish should be subject to the minimum of manipulations such as sorting and transportation during the periods shortly before and after vaccination

10. WITHDRAWAL PERIOD

Zero days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight of children. Store in a refrigerator (+2°C - +8°C). Protect from light. Do not freeze. Shelf-life after dilution according to directions: 5 hours.

12. SPECIAL WARNING(S)

Only vaccinate healthy fish.

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

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

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.

Do not mix with any other veterinary medicinal product.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIAL, IF ANY

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

October 2020

15. OTHER INFORMATION

FOR ANIMAL TREATMENT ONLY.

Package size 1 litre

Batch number: Expiry Date: Vm 01708/4564