PACKAGE LEAFLET

PACKAGE LEAFLET[1]:
AquaVac ERM Oral

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

Marketing authorization 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 Oral Emulsion for rainbow trout

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

Inactivated cells of *Yersinia ruckeri* (Hagerman type I strain):
RPS* >60% after vaccination
(*RPS: relative percentage survival in rainbow trout)
Fish oil

[1] This text will form the label of the product. There is no separate leaflet for this product. The text numbering is taken from the template for the package leaflet. Additional information required by the label template is given under ’15. Other information’.
[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)

Active immunization of rainbow trout, 26 g and above against Enteric Redmouth disease (ERM) to reduce mortality caused by the Hagerman Type I (serotype 01) strain 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 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.

5. CONTRAINDICATIONS

None

6. ADVERSE REACTIONS

None.
If you notice any serious effects or other effects not mentioned on this label, please inform your veterinary surgeon.

7. TARGET SPECIES

Rainbow trout (*Oncorhynchus mykiss).*

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

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.

9. ADVICE ON CORRECT ADMINISTRATION

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.

10. WITHDRAWAL PERIOD(S)

Zero degree days

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight of children.

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

Do not used after the expiry date stated on the label.

Shelf life after first opening the immediate packaging: immediate use
Vaccinetreated feed should be used to complete the vaccine feeding regime within 19 days of being mixed with vaccine.

12. SPECIAL WARNING(S)

Only vaccinate healthy fish. Do not vaccinate fish at water temperatures below 5°C.

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.

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.

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 product should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

October 2020

15. OTHER INFORMATION

FOR ANIMAL TREATMENT ONLY
Vm 01708/4571

Batch No. {number}
EXP {MM/YYYY}
Package size: 1000 ml