PACKAGE LEAFLET

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AquaVac Vibrio Oral

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:
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

The printed package leaflet will state the name and address of the manufacturer responsible for the release of the concerned batch only.

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

AquaVac Vibrio Oral
Oral emulsion

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

Inactivated cells of *Listonella* (*Vibrio) anguillarum* (78-SKID) RPS_{60} > 60% after administration
Inactivated cells of *Vibrio ordalii* (MSC275) RPS_{60} > 60% after administration

Other ingredients
Formaldehyde , fish oil, lecithin, sodium chloride

4. INDICATION(S)

For Rainbow Trout, 12g or over.

For the active immunisation of fish to reduce mortality due to vibriosis caused by *Listonella (Vibrio) anguillarum* and *Vibrio ordalii*.

Onset of immunity: 336 degree-days in case of use of Aquavac Vibrio Oral as a primary vaccine. A duration of immunity has not been demonstrated beyond this.
For fish vaccinated by immersion with Aquavac Vibrio Immersion and Injection and revaccinated with Aquavac Vibrio Oral, protection was seen after 336 degree days.

5. CONTRAINDICATIONS

Do not vaccinate fish during the incubation period of vibriosis.
Do not vaccinate if the water temperature is below 10°C.

6. ADVERSE REACTIONS

No adverse reactions have been reported.
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 vaccine is administered orally, mixed with food pellets, using the following protocol:

<u>Primary vaccination</u>
Day 1-5: 0.02 ml per fish per day
Day 6-10: No vaccine feed
Day 11-15: 0.02 ml per fish per day
Total: 0.2 ml per fish over 10 days

Revaccination scheme after primary vaccination with Aquavac Vibrio immersion and injection: field experience has indicated that immunity to the initial immersion vaccination is at least 3 months. When immunity wanes, the revaccination scheme is recommended.

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 over 10 days

Preparation of vaccine treated feed
Place the vaccine at ambient temperature (20°C) for 1 hour before use so it is more liquid. If 2 distinct phases appear, mix the bottle well until a homogeneous mixture is obtained. Turn the feed pellets slowly and directly pour the vaccine onto the feed. If a sprayer is used, it should be set to deliver a coarse spray without producing aerosol particles, and the spray container must be completely emptied during the mixing operation. Mix well for at least 2 minutes after all the vaccine has been added. Leave the vaccine feed for 1 hour before using to allow the vaccine to penetrate into the pellets well. The vaccine can be mixed with all or part of the daily feed ration.

9. ADVICE ON CORRECT ADMINISTRATION

Not applicable.

10. WITHDRAWAL PERIOD(S)

Zero degree days.

11. SPECIAL STORAGE PRECAUTIONS

Store and transport refrigerated (2 °C –to 8 °C). Do not freeze. Protect from light.
this veterinary medicinal product which is stated on the label
Use entire contents when first opened. Vaccine treated pellets should be used within 10 days of being mixed with vaccine. If the vaccine treated feed is stored, it should be stored in the dark and temperatures should not exceed 16°C. If this temperature is exceeded, the vaccine treated feed may be altered.
Do not use after the expiry date. Keep out of reach and sight of children.

12. SPECIAL WARNING(S)

Only vaccinate healthy fish.
Avoid stress at the time of handling fish, as well as temperature variations. Do not repeat vaccinate fish with AquaVac Vibrio Oral vaccine.

In the absence of specific safety data, the vaccine should not be administered to broodstock or fish intended as broodstock.The vaccine-treated feed should not be used in fungal contamination is noticed.
The minimum weights for fish before vaccination must be respected.

Wear protective gloves when handling the vaccine and vaccine-treated feed.

The vaccine can be used as a revaccination scheme, following a primary vaccination by immersion route with Aquavac Vibrio Immersion and Injection. This scheme has been validated for fish of at least 12g at priming.
No information is available on the safety and efficacy from the concurrent use of this vaccine 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 vaccine or immunological product.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, 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

KEEP OUT OF THE REACH AND SIGHT OF CHILDREN
To be supplied only on veterinary prescription.

Marketing authorisation number: Vm 01708/4570
Manufacturer's batch number {number}
Expiry date {month/year}
Package size 1000 ml