PACKAGE LEAFLET

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AquaVac Vibrio Immersion and Injection

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 Immersion and Injection Concentrate for dip suspension and suspension for intraperitoneal injection.

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

Active substance
Inactivated cells of *Listonella* (*Vibrio*) *anguillarum* strain 78-SKID: RPS_{60} > 75%
Inactivated cells o*f Vibrio* ordalii strain MSC 275: RPS_{60} > 75%

Formaldehyde < 0.5 mg/ml

4. INDICATION(S)

For Rainbow Trout, 2g or over by immersion and 6g or over by injection:
Active immunisation to reduce mortality caused by vibriosis due to *Listonella* (*Vibrio*) *anguillarum* and *Vibrio ordalii*.

The onset of immunity is at least 336 degree days. A duration of immunity of 1200 degree days has been shown.

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 in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Rainbow Trout (*Oncorhynchus mykiss*)

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

Shake well before use.

Administration by immersion (weight at least 2 g)
1. Dilute all of the bottle (1 litre) in 9 litres of hatchery water, clean and suitably oxygenated.
2. Place the fish into batches and immerse for 30 seconds in the diluted vaccine.
3. A litre of vaccine (making 10 litres of diluted vaccine) allows the vaccination of a maximum of 100 kg of fish.

Administration by injection (weight at least 6 g)
1. The vaccine must be administered using a multi-dose injection applicator incorporating a mechanism to prevent flush-back. This applies equally to hand-held and automatic systems.
2. The product is administered by intra-peritoneal injection in the ventral area, just anterior to the pelvic fins. The dose is 0.1 ml per fish.
The fish should be anaesthetised prior to vaccination, using an anaesthetic licensed for use on fish.

9. ADVICE ON CORRECT ADMINISTRATION

Not applicable.

10. WITHDRAWAL PERIOD(S)

Zero degree days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight of children.

Store and transport refrigerated (2 °C –to 8 °C). Protect from light.
Do not freeze.
Do not use after the expiry date stated on the label.

After first opening the immediate packaging: by immersion use immediately;
by injection – use the full contents within 5 hours of the time when bottle cap is broached.

12. SPECIAL WARNING(S)

Only vaccinate healthy fish.

Avoid stress at the time of the handling of fish, as well as temperature variations, in particular between the vaccine suspension and the water of the holding area.
Do not repeat vaccinate fish with AquaVac Vibrio immersion and injection vaccine.

In case of accidental self-injection, seek medical advice immediately and show the package label to the physician.

In the absence of specific safety data, the vaccine should not be administered to broodstock or fish intended as broodstock.
The minimum weights for fish before vaccination must be respected.

The vaccine can be used as a primary vaccination by the immersion route followed by a revaccination with AquaVac Vibrio Oral. 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 of 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

To be supplied only on veterinary prescription
For Animal Treatment Only

Marketing Authorisation number: Vm 01708/4569

Manufacturer's
batch number: {number}
Expiry Date : {month/year}
Package size 1000 ml