PACKAGE LEAFLET

1. Name of the veterinary medicinal product

AquaVac Vibrio Immersion and Injection Concentrate for dip suspension and suspension for injection for rainbow trout

2. Composition

Each 1 ml of vaccine (concentrate) contains:

Active substances:
Vibrio anguillarum, serotype O1, strain 78-SKID, inactivated: RPS_{60} > 75%
Vibrio ordalii[1], strain MSC 275, inactivated: RPS_{60} > 75%

[1] *Vibrio ordalii* is a subset of *Vibrio anguillarum* O2.
(*) RPS_{60}: relative percentage survival in vaccinates, at time of 60% of mortality in controls, after vaccination by injection and subsequent challenge.

Suspension in brown aqueous liquid.

3. Target species

Rainbow Trout (*Oncorhynchus mykiss*).

4. Indications for use

Active immunisation to reduce mortality caused by vibriosis due to *Vibrio anguillarum* and *Vibrio ordalii*.

Onset of immunity: 336 degree days.
Duration of immunity: 1200 degree days.

5. Contraindications

Do not vaccinate fish during the incubation period of vibriosis.

6. Special warnings

Special warnings:
Vaccinate healthy animals only.
Do not vaccinate if the water temperature is below 10 °C.
The minimum weights for fish before vaccination must be respected (see section 8 of the package leaflet).

Special precautions for safe use in the target species:
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.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

Personal protective equipment consisting of guarded needles or needle protectors should be worn when handling the veterinary medicinal product.
In case of accidental self-injection, seek medical advice immediately and show the leaflet or the label to the physician.

Fertility:
In the absence of specific safety data, the vaccine should not be used in broodstock or fish intended as broodstock.

Interaction with other medicinal products and other forms of interaction:
The vaccine can be used as a primary vaccination by immersion followed by a revaccination with AquaVac Vibrio Oral. This scheme has been validated for fish of at least 12 g at priming.

No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product except the product mentioned above. 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.

Overdose:
No adverse events have been noted following a double dose of the vaccine in trout.

Major incompatibilities:
Do not mix with any other veterinary medicinal product.

7. Adverse events

No adverse events have been reported.
Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder <or the local representative of the marketing authorisation holder> using the contact details at the end of this leaflet, or via your national reporting system: {national system details}.

8. Dosage for each species, routes and method of administration

For Rainbow trout, 2 g or over by immersion and 6g or over by intraperitoneal use .

Administration by immersion (weight at least 2 g)
1. Dilute the content 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 intraperitoneal use (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 intraperitoneal 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

Shake well before use.

10. Withdrawal periods

Zero degree days.

11. Special storage precautions

Keep out of the sight and reach of children.

Store and transport refrigerated (2 °C – 8 °C).
Do not freeze.
Protect from light.
Do not use this veterinary medicinal product after the expiry date which is stated on the label. The expiry date refers to the last day of that month.

Shelf life after first opening the immediate packaging:
Vaccination by immersion: use immediately;
Vaccination by intraperitoneal use: use the full contents within 5 hours of the time when bottle cap is broached.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater <or household waste>.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

Ask your <veterinary surgeon> <or> <pharmacist> how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

[MA number]

Pack size:
1000 ml

15. Date on which the package leaflet was last revised

{MM/YYYY}
Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

16. Contact details

Marketing authorisation holder <and manufacturer responsible for batch release> <and contact details to report suspected adverse reactions>:

<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

<Local representatives <and contact details to report suspected adverse reactions>:>

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

17. Other information