SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE IMMUNOLOGICAL VETERINARY MEDICINAL PRODUCT

Aquavac Vibrio Oral

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substances	**Quantity**
Inactivated cells of *Listonella* (*Vibrio*) *anguillarum* strain 78-SKID	RPS_{60}(*) > 60% after administration
Inactivated cells of *Vibrio) ordalii*[1] strain MSC275	RPS_{60}(*) > 60% after administration

(*) RPS_{60} : relative percentage survival in vaccinates, at time of 60% of mortality in controls, after oral vaccination and subsequent challenge

Excipient	
Formaldehyde	< 0.5 mg/ml

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Oral emulsion
Pale yellow emulsion

4. CLINICAL PARTICULARS:

4.1 Target species

Rainbow Trout (*Oncorhynchus mykiss*)

4.2 Indications for use, specifying the target species

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.

4.3 Contraindications

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

[1] *Vibrio ordalii* is a subset of *Listonella* (*Vibrio) anguillarum* O2

4.4 Special warnings for each target species

The minimum weights for fish before vaccination must be respected.

4.5 Special precautions for use

Special precautions for use in animals
Only vaccinate healthy fish
Avoid stress at the time of the handling of fish, as well as temperature variations.
Do not repeat vaccinate fish with AquaVac Vibrio Oral vaccine.
The vaccine-treated feed should not be used if fungal contamination is noticed.

Special precautions to be taken by the persons administering the veterinary medicinal product to animals.
Wear protective gloves when handling the vaccine and the vaccine-treated feed.

4.6 Adverse reactions (frequency and seriousness)

None reported

4.7 Use during pregnancy, lactation or lay

In the absence of specific safety data, the vaccine should not be administered to broodstock or fish intended as broodstock.

4.8 Interaction with other medicinal products and other forms of interaction

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.

4.9 Amounts to be administered and administration route

The vaccine is administered orally, mixed with food pellets, using the following protocol:
Primary vaccination
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 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.

4.10 Overdose (symptoms, emergency procedures, antidotes) (if necessary)

No adverse effects have been noted following a double dose of the vaccine in trout.

4.11 Withdrawal period(s)

Zero degree days.

5. IMMUNOLOGICAL PROPERTIES

ATC Vet code QI10BB01
The vaccine induces active immunity against vibriosis due to *Listonella* (*Vibrio*) *anguillarum* and *Vibrio ordalii*.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Formaldehyde
Sodium chloride
Fish oil
Lecithin

6.2 Incompatibilities

Do not mix with any other vaccine or immunological product.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 3 years
Shelf-life of vaccine-treated feed: 10 days

6.4 Special precautions for storage

Store and transport refrigerated (2°C to 8°C). Protect from light. Do not freeze.

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.

6.5 Nature and composition of immediate packaging

Nature of immediate packaging:
High density polyethylene bottle with bromobutyl stopper and aluminium seal.

1000 ml bottle (10 000 doses as revaccination scheme, 5000 doses as primary vaccination).

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from use of such products, 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.

7. MARKETING AUTHORISATION HOLDER

MSD Animal Health UK Limited
Walton Manor
Walton
Milton Keynes
Buckinghamshire
MK7 7AJ

8. MARKETING AUTHORISATION NUMBER

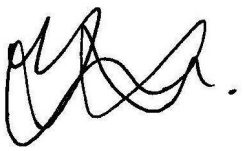
Vm 01708/4570

9. DATE OF FIRST AUTHORISATION

20 December 2006

10. DATE OF REVISION OF TEXT

August 2020



Approved: 14 August 2020