

**IRISH MEDICINES BOARD ACT 1995**

**ANIMAL REMEDIES REGULATIONS, 2005**

**(S.I. No. 734 of 2005)**

VPA:10277/095/001

Case No: 7001015

The Irish Medicines Board in exercise of the powers conferred on it by Animal Remedies Regulations (S.I. No. 734 of 2005) hereby grants to:

**Schering Plough Limited**

**Shire Park, Welwyn Garden City, Hertfordshire AL7 1TW, United Kingdom**

an authorisation, subject to the provisions of the said Regulations and the general conditions of the attached authorisation, in respect of the Veterinary Medicinal Product:

**AquaVac Vibrio Oral**

The particulars of which are set out in Part 1 and Part 2 of the said Schedule. The authorisation is also subject to any special conditions as may be specified in Part 2 of the said Schedule.

This authorisation, unless previously revoked, shall continue in force from **05/07/2006** to **04/07/2011**.

Signed on behalf of the Irish Medicines Board

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A person authorised in that behalf by the said Board.

## Part II

### Summary of Product Characteristics

#### 1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Aquavac Vibrio Oral

#### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

##### Active ingredient

Inactivated cells of *Listionella (Vibrio) anguillarum* strain 78-SKID

Inactivated cells of *Vibrio ordalii* strain MSC275

##### Quantity

RPS<sub>60</sub>(\*) > 60%

after administration

RPS<sub>60</sub>(\*) > 60%

after administration

##### Other constituents

Formaldehyde

< 0.5 mg/mL

Excipient

QSP 1 mL

(\*) RPS<sub>60</sub> : relative percentage survival in vaccinates, at time of 60% of mortality in controls, after oral vaccination and subsequent challenge

*Vibrio ordalii* is a subset of *Listionella (Vibrio) anguillarum* O2

#### 3 PHARMACEUTICAL FORM

Oral emulsion

Pale yellow emulsion

#### 4 CLINICAL PARTICULARS

##### 4.1 Target Species

Rainbow trout (*Oncorhynchus mykiss*), 12 g or over.

##### 4.2 Indications for use, specifying the target species

For Rainbow Trout:

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

*Vibrio ordalii* is a subset of *Listionella (Vibrio) anguillarum* O2

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.

#### 4.4 Special warnings for each target species

The minimum weights for fish before vaccination must be respected (see Target Species).

#### 4.5 Special precautions for use

##### (i) *Special precautions for use in animals*

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. Only vaccinate healthy fish

The vaccine-treated feed should not be used if fungal contamination is noticed.

##### (ii) *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-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 12 g at priming.

No information is available on the safety and efficacy from the concurrent use of this vaccine with any other vaccines or medicaments. It is therefore recommended that no other vaccine should be administered within 168 degree days (14 days at 12°C) before and after vaccination with AquaVac Vibrio Oral.

#### 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 course 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 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES**

The vaccine induces active immunity against vibriosis due to *Listionella (Vibrio) anguillarum* and *Vibrio ordalii*.

*Vibrio ordalii* is a subset of *Listionella (Vibrio) anguillarum* O2.

ATC Vet code QI10BB01

### **6 PHARMACEUTICAL PARTICULARS**

#### **6.1 List of excipients**

Formaldehyde (declared in product literature),  
Sodium chloride,  
Fish oil  
Lecithin

#### **6.2 Incompatibilities**

Do not mix with any other vaccine or immunological product.

#### **6.3 Shelf-life**

3 years  
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**

High density polyethylene bottle  
Bromobutyl stopper  
Aluminium seal

#### Administrative identification of unit intended for sale:

1L bottle (10 000 dose as revaccination scheme, 5000 dose as primary vaccination)

**6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials**

Any unused product or waste materials should be disposed of in accordance with national requirements.

**7 MARKETING AUTHORISATION HOLDER**

Schering Plough Ltd,  
Shire Park,  
Welwyn Garden City,  
Hertfordshire,  
AL7 1TW,  
United Kingdom

**8 MARKETING AUTHORISATION NUMBER(S)**

VPA 10277/95/1

**9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

5th July 2006

**10 DATE OF REVISION OF THE TEXT**

None