IRISH MEDICINES BOARD ACT 1995

ANIMAL REMEDIES REGULATIONS, 2005

(S.I. No. 734 of 2005)

VPA:**10277/096/001**
Case No: 7001018

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 Immersion & Injection

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 Immersion and Injection
Aquavac Vibrio (vet) - Denmark

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

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

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

Vibrio ordalli is a subset of *Listonella (Vibrio) anguillarum* O2

Other constituents
Formaldehyde ≤ 0.5 mg/mL

3 PHARMACEUTICAL FORM

Concentrate for dip suspension & Suspension for intraperitoneal use
Suspension in brown aqueous liquid

4 CLINICAL PARTICULARS

4.1 Target Species

Rainbow trout (*Oncorhynchus mykiss*), 2 g or over by immersion and 6 g or over by injection.

4.2 Indications for use, specifying the target species

For Rainbow Trout
Active immunisation to reduce mortality caused by vibriosis due to *Listonella* (*Vibrio*) *anguillarum* and *Vibrio ordalii*[1].
The onset of immunity is at least 336 degree days. A duration of immunity of 1200 degree days has been shown.

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

Special precautions for use in animals
Only vaccinate healthy fish.
Do not repeat vaccinate fish with Aquavac Vibrio immersion and injection vaccine.
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.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
In case of accidental self-injection, seek medical advice immediately and show the package label to the physician.

4.6 Adverse reactions (frequency and seriousness)

None known

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 primary vaccination by immersion route, 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 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 Immersion and Injection'.

4.9 Amounts to be administered and administration route

Shake the bottle before use

Administration by immersion (weight at least 2 g)
Dilute all of the bottle (1 litre) in 9 litres of hatchery water, clean and suitably oxygenated.
Place the fish into batches and immerse for 30 seconds in the diluted vaccine.
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)
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.
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.

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 *Listonella* (*Vibrio*) *anguillarum* and *Vibrio ordalii*

Vibrio ordalli is a subset of *Listonella (Vibrio) anguillarum* O2

ATC Vet code QI10BB01

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Formaldehyde (declared in product literature)
Sodium chloride

6.2 Incompatibilities

Do not mix with any other vaccine or immunological product

6.3 Shelf-life

24 months
Once broached, the entire bottle should be used

After opening : Vaccination by immersion: use immediately

Vaccination by injection: use the full contents within 5 hours of the time when the bottle cap is broached.

6.4 Special precautions for storage

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

6.5 Nature and composition of immediate packaging

Nature of immediate packaging
High density polyethylene bottle
Bromobutyl stopper
Aluminium seal

Administrative identification of unit intended for sale:
1L bottle (10000 dose by injection, 100kg of fish by immersion 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 Limited
Shire Park,
Welwyn Garden City
Hertfordshire, AL7 1TW
England

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10277/96/1

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

5th July 2006

10 DATE OF REVISION OF THE TEXT

None