SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

AquaVac Vibrio Immersion and Injection
DK: AquaVac Vibrio (vet)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substances:
Inactivated cells of *Listonella* (*Vibrio*) *anguillarum* strain 78-SKID: RPS_{60}(*) > 75%
Inactivated cells o*f Vibrio* ordalii[1] 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

Excipient

Formaldehyde	< 0.5 mg/ml

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Concentrate for dip suspension and Suspension for intraperitoneal injection.
Suspension in brown aqueous liquid.

4 CLINICAL PARTICULARS

4.1 Target Species

Rainbow trout (*Oncorhynchus mykiss*)

4.2 Indications for Use, Specifying the Target Species

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.

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.

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.

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

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 leaflet/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 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
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 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

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: 2 years

Shelf life after first opening the immediate packaging:
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 with bromobutyl stopper and aluminium seal.

1000 ml bottle (10000 doses by injection, 100kg of fish by immersion vaccination).

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

Intervet International BV
Wim de Körverstraat 35
5831AN Boxmeer
The Netherlands

Represented by the national companies in the concerned member states.

8 MARKETING AUTHORISATION NUMBER(S)

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION.

12-01-2005 / 05-07-2011

10 DATE OF REVISION OF THE TEXT

May 2011

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.