

I. SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

AquaVac Strep *Sa*

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Per ml of vaccine:

Active substance(s)

1.36 x 10⁸ bacterial cells of *Streptococcus agalactiae* TI 513

Adjuvant:

ISA 763A VG

3. PHARMACEUTICAL FORM

Emulsion for injection.

4. CLINICAL PARTICULARS

4.1 Target species

Fish.

4.2 Indications for use

For active immunization of susceptible fish species (see also 4.4) to reduce mortality and disease due to Streptococcosis caused by *Streptococcus agalactiae*¹.

Onset of immunity demonstrated from 3 weeks after vaccination at a water temperature of 28°C. Duration of immunity demonstrated for at least 30 weeks after a single vaccination.

In the field it has been observed that the food conversion rate is significantly improved in vaccinated fish under disease pressure.

4.3 Contraindications

None known.

4.4 Special warnings (for each target species)

The vaccine has been tested for safety and efficacy in Tilapia (*Oreochromis* sp.) as a representative species. The vaccine may be used in other fish species. However, if so, its use should be undertaken with care and it is advisable to test the vaccine on a small number of fish prior to mass vaccination.

4.5 Special precautions for use, including special precautions to be taken by the person administering the veterinary medicinal product to animals

Personal protective equipment consisting of e.g. needle protector should be used when handling the product. In case of accidental self-injection, seek medical advice immediately and show the package insert or label to the physician.

To the user:

This product contains oil. Accidental injection/self injection may result in severe pain and swelling, particularly if injected into a joint or finger, and in rare cases could result in the loss of the affected finger if prompt medical attention is not given.

If you are accidentally injected with this product, seek prompt medical advice even if only a very small amount is injected and take the package leaflet with you.

¹ Previously known as *Streptococcus difficilis*

If pain persists for more than 12 hours after medical examination, seek medical advice again.

To the physician:

This product contains oil. Even if small amounts have been injected, accidental injection with this product can cause intense swelling, which may, for example, result in ischaemic necrosis and even the loss of a digit. Expert, PROMPT, surgical attention is required and may necessitate early incision and irrigation of the injected area, especially where there is involvement of finger pulp or tendon.

4.6 Adverse reactions

A small population of treated animals may show very minor lesions.

4.7 Use in broodstock animals

No adverse reaction expected.

4.8 Interaction with other medicinal products and other forms of interaction

No information is available on the compatibility of this vaccine with any other.

4.9 Amounts to be administered and administration route

Inject 0.05 ml intraperitoneally in fish of minimum 15 gram. Ensure the needle penetrates through the muscle wall and ideally deposits the vaccine into the visceral fatty area. For example, in barramundi (*Lates calcarifer*) and tilapia (*Oreochromis spp*) of 15 gram this is between and just before the tip of the pelvic fins. This is to ensure the needle does not penetrate important internal organs such as the liver, stomach and spleen.

Shake the vaccine well before use.

Sterile injection equipment should be used.

For injection, fish should be anaesthetised.

Food should be withheld for a period of 1 day prior to vaccination.

Avoid stress in the period prior to and after vaccination.

4.10 Overdose

No other symptoms expected than those indicated in 4.6.

4.11 Withdrawal period

Zero days.

5. IMMUNONOLOGICAL PROPERTIES

To stimulate active immunity against strains of *Streptococcus agalactiae* covered by the vaccine strain.

6. PHARMACEUTICAL PARTICULARS

6.1 Incompatibilities

None known.

6.2 Shelf life

Shelf-life of the product as packaged for sale: 3 year

Opened bottles should be used promptly (within 5 hours) and should not be stored.

6.3 Special precautions for storage

Store at 2 - 8°C. Protect from light. Do not freeze.

6.4 Nature and contents of container

PET or glass bottles closed with a rubber stopper and sealed with a coded aluminium cap.
Package size: 50 ml (1 000 doses), 100 ml (2 000 doses), 250 ml (5 000 doses), 500 ml (10 000 doses) or 1 000 ml (20 000 doses). Not all pack sizes may be marketed.

6.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Any unused vaccine or waste materials should be disposed of in accordance with the local requirements.

7. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Intervet International BV