

**I. SUMMARY OF PRODUCT CHARACTERISTICS****1. NAME OF THE IMMUNOLOGICAL VETERINARY MEDICINAL PRODUCT**  
AquaVac Strep Si**2. QUALITATIVE AND QUANTITATIVE COMPOSITION**  
Per ml of vaccine:Active substance(s)

1 x 10<sup>10</sup> bacterial cells of *Streptococcus iniae* SB 430\*

Adjuvants and/or preservative:

None

\* The final product may contain traces of formaldehyde (≤ 0.05% free) from the inactivation of the antigen.

**3. PHARMACEUTICAL FORM**

Suspension for immersion or injection

**4. IMMUNOLOGICAL PROPERTIES**

The bacterial active ingredient is an inactivated strain of *Streptococcus iniae* which stimulates active immunity to aid in the control of outbreaks of streptococcal disease caused by *Streptococcus iniae*.

**5. CLINICAL PARTICULARS****5.1 Target species**

Fish species susceptible to *Streptococcus iniae* infections.

**5.2 Indications for use, specifying the target species**

Aid in the protection against *Streptococcus iniae* infections in susceptible fish species (see also 5.10).

**5.3 Contraindications**

Unhealthy fish should not be vaccinated.

**5.4 Undesirable effects (frequency and seriousness) in the target species**

None known (see also 5.10)

**5.5 Special precaution(s) for use**

Vaccination by dip immersion is recommended from 3 grams and onwards and vaccination by intraperitoneal injection is recommended from 20 gram and onwards. Feed should be withheld from fish for a period of 1 day prior to vaccination. For injection, fish should be anaesthetised. Start feeding, at the earliest, 12 hours after vaccination. Avoid stress in the period prior to and after vaccination. Shake the bottle well before use. For injection sterile injection equipment should be used.

**5.6 Use during pregnancy and lactation**

Not applicable

**5.7 Interaction with other vaccines and medicaments when administered in combination with the product**

Not known. The product is recommended for healthy fish only, which means that fish should not be under medical treatment at the time of vaccination. Do not administer in conjunction with systemic treatments.

**5.8 Posology and method of administration**

The preferred method for vaccination is by intraperitoneal injection. If early protection is needed, fish can be vaccinated by dip immersion. However, this alone is not sufficient to achieve a long duration of protection. Therefore, the fish should be re-vaccinated by injection as soon as the size of the fish allows for this.

Vaccination by intraperitoneal injection:

Inject 0.1 ml vaccine intraperitoneally at the ventral side of the fish. Ensure the needle penetrates through the muscle wall and ideally deposits the vaccine in the peritoneal cavity where the visceral fat is located. For example, in barramundi (*Lates calcarifer*) and tilapia (*Oreochromis spp*) of 20 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.

Vaccination by dip immersion:

One litre of vaccine is mixed with 9 litres of seawater. Using a knot-less hand net, immerse 1 kg of fish into this vaccine solution for 30 seconds. Prepare a new vaccine solution after having vaccinated 50 kg of fish. Ensure good oxygenation or aeration during immersion vaccination. Maintain pH and temperature stable throughout.

**5.9 Overdose (symptoms, emergency procedures, antidotes) (if necessary)**

No particular symptoms at double-dose intraperitoneal vaccination or double-dose and double-time immersion vaccination.

**5.10 Special warnings for each target species**

The vaccine has been tested for safety and efficacy in Asian seabass (Barramundi, *Lates calcarifer*) 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.

**5.11 Withdrawal period**

Zero days

**5.12 Special precautions to be taken by the person administering the veterinary medicinal product to animals**

Protective equipment (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.

**6. PHARMACEUTICAL PARTICULARS****6.1 Major incompatibilities**

Do not mix with other products

**6.2 Shelf life**

Three year when stored at 2 to 8°C. Opened bottles should be used the same day and should not be stored.

## I. SUMMARY OF PRODUCT CHARACTERISTICS

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**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.

**6.5 Special precautions for the disposal of unused medicinal product or waste material, if any**

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

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**ANNEX A. LABELLING****1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

AquaVac Strep Si

**2. COMPOSITION PER DOSE**1 x 10<sup>10</sup> bacterial cells of *Streptococcus iniae* SB 430 per ml of vaccine.**3. PACKAGE SIZE**

100 ml or 250 ml or (500 ml) or (1000 ml)

**4. INDICATION(S)**Aid in the protection against *Streptococcus iniae* infections in susceptible fish species.**5. METHOD AND ROUTE(S) OF ADMINISTRATION**

Suspension for the immersion or injection.

For details, see package insert.

Vaccination by injection: Inject 0.1 ml vaccine intraperitoneally.Vaccination by dip immersion: One litre of vaccine is mixed with 9 litres of seawater. Using a knot-less hand net, immerse 1 kg of fish into this vaccine solution for 30 seconds. Prepare a new vaccine solution after having vaccinated 50 kg of fish. Ensure good oxygenation or aeration during immersion vaccination. Maintain pH and temperature stable throughout.**6. EXPIRY DATE**

EXP:

**7. SPECIAL STORAGE CONDITIONS**

Shake well before use. Store and transport at 2-8°C. Do not freeze.

**8. THE WORDS "FOR ANIMAL TREATMENT ONLY"**

For animal treatment only

**9. WITHDRAWAL PERIOD**

Zero days

**10. PRODUCT OF INTERVET INTERNATIONAL B.V.  
BOXMEER - HOLLAND****11. MANUFACTURER'S BATCH NUMBER**

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**ANNEX B. PACKAGE INSERT**

- 1. NAME OF THE VETERINARY MEDICINAL PRODUCT**  
AquaVac Strep Si
- 2. STATEMENT OF THE ACTIVE SUBSTANCE(S)**  
1 x 10<sup>10</sup> bacterial cells of *Streptococcus iniae* SB 430 per ml of vaccine.
- 3. PRODUCT OF INTERVET INTERNATIONAL  
BOXMEER - HOLLAND**
- 4. TARGET SPECIES**  
Fish species susceptible to *Streptococcus iniae* infections.
- 5. INDICATION(S)**  
Aid in the protection against *Streptococcus iniae* infections in susceptible fish species (see under 11 below).
- 6. DOSAGE FOR EACH SPECIES**  
The preferred method for vaccination is by intraperitoneal injection from 20 gram and onwards. If early protection is needed fish can be vaccinated by dip immersion from 3 gram and onwards. However, this alone is not sufficient to achieve a long duration of protection. Therefore, the fish should be re-vaccinated by intraperitoneal injection as soon as the size of the fish allows for this.
- 7. ADVICE ON CORRECT ADMINISTRATION**  
Vaccination by intraperitoneal injection: Inject 0.1 ml vaccine intraperitoneally. Ensure the needle penetrates through the muscle wall and ideally deposits the vaccine in the peritoneal cavity where the visceral fat is located. For example, in barramundi (*Lates calcarifer*) and tilapia (*Oreochromis spp*) of 20 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.  
Vaccination by dip immersion: 1 litre of vaccine is mixed with 9 litres of seawater. Using a knot-less hand net, immerse 1 kg of fish into this vaccine solution for 30 seconds. Prepare a new vaccine solution after having vaccinated 50 kg fish. Ensure good oxygenation or aeration during immersion vaccination. Maintain pH and temperature stable throughout.
- 8. CONTRA-INDICATIONS**  
Unhealthy fish should not be vaccinated.
- 9. WITHDRAWAL PERIOD**  
Zero days
- 10. SPECIAL STORAGE CONDITIONS, IF ANY**  
Store at 2 - 8°C. Protect from light. Do not freeze.
- 11. SPECIAL WARNINGS, IF NECESSARY**  
In case of accidental self-injection, seek medical advice immediately and show the package insert or label to the physician.

The vaccine has been tested for safety and efficacy in Asian seabass (Barramundi, *Lates calcarifer*) as a representative species. The vaccine may be used in other fish species.

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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.

**12. DATE ON WHICH THE PACKAGE INSERT WAS LAST REVISED**

Date:

**13. OTHER INFORMATION**

For animal treatment only.