1. SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Aquavac Strep *Sa-Si*

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Per ml of vaccine:

Active substances:
Inactivated bacterial cells of *Streptococcus agalactiae* TI513, serotype Ib
Inactivated bacterial cells of *Streptococcus iniae* SB430

Excipients:
Adjuvant: Light liquid paraffin

3. PHARMACEUTICAL FORM

Emulsion for injection.

4. CLINICAL PARTICULARS

4.1 Target species

Fish species susceptible to *Streptococcus agalactiae* (serotype Ib) and *Streptococcus iniae* infections.

4.2 Indications for use, specifying the target species

For active immunization of susceptible fish species to reduce mortality and disease due to streptococcosis caused by *Streptococcus agalactiae* (serotype Ib) and *Streptococcus iniae*.

Onset of immunity has been demonstrated from 1 week after vaccination at a water temperature of 28°C. Duration of immunity has been demonstrated for at least 12 weeks. In the field, efficacy has been demonstrated during the entire production period (at least 6 months).

4.3 Contraindications

None.

4.4 Special precautions 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.

Vaccinate healthy fish only.

4.5 Special precautions for use

Special precautions for use in animals
Do not vaccinate fish with a weight less than 10 grams.

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 leaflet or the label to the physician.

To the user:
This veterinary medicinal product contains mineral 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. If pain persists for more than 12 hours after medical examination, seek medical advice again.

To the physician:
This veterinary medicinal product contains mineral 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
After vaccination, fish appetite may be reduced until 1 day post vaccination. Mild transient local reactions (adhesions) may be observed.

4.7 Use in brood stock animals
Do not vaccinate reproductive fish.

4.8 Interaction with other medicinal products and other forms of interaction
No information is available on the safety and efficacy of this vaccine when used 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
Inject a single dose of 0.05 ml intraperitoneally at the ventral side of fish with a minimum weight of 10 grams.
Ensure the needle penetrates through the muscle wall and deposits the vaccine into the peritoneal cavity where the visceral fat is located. For example, in tilapia (*Oreochromis* spp.) 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.

Food should be withheld from fish for a period of 1 day prior to vaccination. Start feeding, at the earliest, 12 hours after vaccination.
Fish should be anaesthetised before injection. Sterile injection equipment should be used.
Avoid stress in the period prior to and after vaccination.
Shake the bottle well before use without generating air bubbles.

4.10 Overdose

After double dose vaccination, fish appetite may be reduced until 3 days post vaccination. Mild transient local reactions (adhesions) may be observed.

4.11 Withdrawal period

Zero days.

5. IMMUNONOLOGICAL PROPERTIES

The product stimulates active immunity against streptococcosis caused by *Streptococcus agalactiae* (serotype Ib) and *Streptococcus iniae*.

6. PHARMACEUTICAL PARTICULARS

6.1 Incompatibilities

Do not mix with any other veterinary medicinal product.

6.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 24 months.

6.3 Special precautions for storage

Store at 2°C - 8°C. Protect from light. Do not freeze.
Once opened, all the contents of the bottle should be used within one day and should not be stored.

6.4 Nature and contents of container

Plastic bottles closed with a rubber stopper and sealed with a coded aluminium cap.
Pack size: 250 ml (5 000 doses).

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 B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
The Netherlands

As represented by the national company.

ANNEX A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE OR ON THE IMMEDIATE PACKAGE *(Bottle)*

1. NAME OF THE VETERINARY MEDICINAL PRODUCT
Aquavac Strep *Sa-Si*

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES
Per ml of vaccine:

Active substances:
Inactivated bacterial cells of *Streptococcus agalactiae* TI513, serotype Ib
Inactivated bacterial cells of *Streptococcus iniae* SB430

Excipients:
Adjuvant: Light liquid paraffin

3. PHARMACEUTICAL FORM
Emulsion for injection

4. PACKAGE SIZE
250 ml (5000 doses)

5. TARGET SPECIES
Fish species susceptible to *Streptococcus agalactiae* (serotype Ib) and *Streptococcus iniae* infections.

6. INDICATION(S)
For active immunization of susceptible fish species to reduce mortality and disease due to streptococcosis caused by *Streptococcus agalactiae* (serotype Ib) and *Streptococcus iniae*.

7. METHOD AND ROUTE(S) OF ADMINISTRATION
Intraperitoneal use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD
Zero days.

9. SPECIAL WARNINGS, IF NECESSARY
Do not vaccinate fish with a weight less than 10 grams.
Accidental self-injection is dangerous – read package leaflet before use.

10. EXPIRY DATE
EXP:

11. SPECIAL STORAGE CONDITIONS
Store at 2°C - 8°C. Protect from light. Do not freeze.
Once opened, all the contents of the bottle should be used within one day and should not be stored.

12. SPECIAL PRECAUTIONS FOR THE DISPOSDAL OF UNUSED PRODUCT OR WASTE MATERIAL, IF ANY

Disposal: Read package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Product of Intervet International B.V., Boxmeer, the Netherlands, as represented by the national company

16. MANUFACTURER'S BATCH NUMBER

LOT: ……..

ANNEX B. PACKAGE INSERT

1. NAME OF THE VETERINARY MEDICINAL PRODUCT
Aquavac Strep *Sa-Si*

2. STATEMENT OF THE ACTIVE SUBSTANCE(S)
Per ml of vaccine:

Active substances:
Inactivated bacterial cells of *Streptococcus agalactiae* TI513, serotype Ib
Inactivated bacterial cells of *Streptococcus iniae* SB430

Excipients:
Adjuvant: Light liquid paraffin

3. PRODUCT OF INTERVET INTERNATIONAL BOXMEER – THE NETHERLANDS

4. TARGET SPECIES
Fish species susceptible to *Streptococcus agalactiae* (serotype Ib) and *Streptococcus iniae* infections.

5. INDICATION(S)
For active immunization of susceptible fish species to reduce mortality and disease due to streptococcosis caused by *Streptococcus agalactiae* (serotype Ib) and *Streptococcus iniae*.

Onset of immunity has been demonstrated from 1 week after vaccination at a water temperature of 28°C. Duration of immunity has been demonstrated for at least 12 weeks. In the field, efficacy has been demonstrated during the entire production period (at least 6 months).

6. CONTRAINDICATIONS
None.

7. ADVERSE REACTIONS
After vaccination, fish appetite may be reduced until 1 day post vaccination. Mild transient local reactions (adhesions) may be observed.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINSTRATION
Inject a single dose of 0.05 ml intraperitoneally at the ventral side of fish with a minimum weight of 10 grams.

9. ADVICE ON CORRECT ADMINISTRATION
Ensure the needle penetrates through the muscle wall and deposits the vaccine into the peritoneal cavity where the visceral fat is located. For example, in tilapia (*Oreochromis* spp.) 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.

Food should be withheld from fish for a period of 1 day prior to vaccination. Start feeding, at the earliest, 12 hours after vaccination.

Fish should be anaesthetised before injection. Sterile injection equipment should be used.
Avoid stress in the period prior to and after vaccination.
Shake the bottle well before use without generating air bubbles.

10. WITHDRAWAL PERIOD

Zero days.

11. SPECIAL STORAGE CONDITIONS

Store at 2 - 8°C. Protect from light. Do not freeze.
Once opened, all the contents of the bottle should be used within one day and should not be stored.

12. SPECIAL WARNINGS

Special precautions 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.

Vaccinate healthy fish only.

Special precautions for use in animals
Do not vaccinate fish with a weight less than 10 grams.

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 leaflet or the label to the physician.

To the user:
This veterinary medicinal product contains mineral 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. If pain persists for more than 12 hours after medical examination, seek medical advice again.

To the physician:
This veterinary medicinal product contains mineral 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.

Use in brood stock animals
Do not vaccinate reproductive fish.

Interaction with other medicinal products and other forms of interaction
No information is available on the safety and efficacy of this vaccine when used 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.

Overdose
After double dose vaccination, fish appetite may be reduced until 3 days post vaccination. Mild transient local reactions (adhesions) may be observed.

Incompatibilities
Do not mix with any other veterinary medicinal product.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

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

14. OTHER INFORMATION

For veterinary use only.