1. SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

AquaVac® TenaSi

2. QUALITATIVE COMPOSITION

Active substance(s)
Per dose:
Inactivated bacterial cells of *Streptococcus iniae*
Inactivated bacterial cells of *Tenacibaculum maritimum*

Adjuvant:
Oil adjuvant

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 due to Streptococcosis caused by *Streptococcus iniae* and Tenacibaculosis caused by *Tenacibaculum maritimum*.

Onset of immunity: from 1 week after vaccination at a water temperature of 28°C (196 degrees days), reaching full immunity at two weeks after vaccination for *T. maritimum*.

Duration of immunity: at least 12 weeks after vaccination.

4.3 Contraindications

None known.

4.4 Special warnings (for each target species)

The vaccine has been tested for safety and efficacy in Asian sea bass (*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.

4.5 Special precautions for use

Special precautions for use in animals

Fish should be healthy and free of disease at the time of vaccination. Sick or weak fish may not develop adequate immunity.

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. 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 slight local reactions.

4.7 Use in broodstock animals
No adverse reaction expected.

4.8 Interaction with other medicinal products and other forms of interaction
The vaccine can be used in combination with other compatible oil based injection vaccines from the AquaVac vaccine range, such as AquaVac® IridoV.

No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product except the product range mentioned above. 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
Food should be withheld for a period of 1 day prior to vaccination.
Avoid stress in the period prior to and after vaccination.
Sterile injection equipment should be used.
For injection, fish should be anaesthetised.
Shake the vaccine well before use.

Inject 0.05 ml intraperitoneally halfway between the base and tip of the pelvic fins in fish of minimum 10 gram.

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 iniae* and *Tenacibaculum maritimum*.

6. PHARMACEUTICAL PARTICULARS

6.1 Incompatibilities

Do not mix with any other veterinary medicinal products except the above mentioned product range.

6.2 Shelf life

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

Plastic or glass bottles closed with a rubber stopper and sealed with an aluminium cap.
Package size: 50 ml, 100 ml, 250 ml or 500 ml. 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 B.V.

ANNEX A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE OR ON THE IMMEDIATE PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT
AquaVac® TenaSi

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES
Inactivated bacterial cells of *Streptococcus iniae* and *Tenacibaculum maritimum*.
Oil adjuvant.

3. INDICATIONS FOR USE
Vaccine against *Streptococcus iniae* and *Tenacibaculum maritimum*.

4. PACKAGE SIZE
50 ml (1,000 doses), 100 ml (2,000 doses), 250 ml (5,000 doses), or 500 ml (10,000 doses)

5. METHOD AND ROUTE(S) OF ADMINISTRATION
Inject 0.05 ml intraperitoneally halfway between the base and tip of the pelvic fins in fish of minimum 10 gram. For details, see package insert.

6. EXPIRY DATE
EXP:

7. SPECIAL STORAGE CONDITIONS
Shake well before use. Store dark at 2-8°C. Do not freeze.

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"
For animal treatment only

9. THE WORDS "KEEP OUT OF REACH AND SIGHT OF CHILDREN"
Keep out of reach and sight of children

10. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER
Product of Intervet International B.V.
Boxmeer – the Netherlands

11. MANUFACTURER'S BATCH NUMBER
LOT: ……..

ANNEX B. PACKAGE LEAFLET

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

AquaVac® TenaSi

2. STATEMENT OF THE ACTIVE SUBSTANCE(S)

Active substance(s)
Per dose:
Inactivated bacterial cells of *Streptococcus iniae*
Inactivated bacterial cells of *Tenacibaculum maritimum*

Adjuvant:
Oil adjuvant

3. PRODUCT OF INTERVET INTERNATIONAL BOXMEER – THE NETHERLANDS

4. INDICATION(S)

For active immunization of susceptible fish species to reduce mortality due to Streptococcosis caused by *Streptococcus iniae* and Tenacibaculosis caused by *Tenacibaculum maritimum*.

Onset of immunity: from 1 week after vaccination at a water temperature of 28°C (196 degrees days), reaching full immunity at two weeks after vaccination for *T. maritimum*.

Duration of immunity: at least 12 weeks after vaccination.

5. CONTRA-INDICATIONS

None known.

6. ADVERSE REACTIONS

A small population of treated animals may show very slight local reactions.

7. TARGET SPECIES

Fish.

8. DOSAGE FOR EACH SPECIES

0.05 ml.

9. ADVICE ON CORRECT ADMINISTRATION

Food should be withheld for a period of 1 day prior to vaccination.
Avoid stress in the period prior to and after vaccination.
Sterile injection equipment should be used.
For injection, fish should be anaesthetised.
Shake the vaccine well before use.

Inject 0.05 ml intraperitoneally halfway between the base and tip of the pelvic fins in fish of minimum 10 gram.

10. WITHDRAWAL PERIOD

Zero days.

11. SPECIAL STORAGE PRECAUTIONS

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

12. SPECIAL WARNINGS, IF NECESSARY

Special precautions for use in animals

The vaccine has been tested for safety and efficacy in Asian sea bass (*Lates calcarifer*) as 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.

Fish should be healthy and free of disease at the time of vaccination. Sick or weak fish may not develop adequate immunity.

The vaccine can be used in combination with other compatible oil based injection vaccines from the AquaVac vaccine range, such as AquaVac® IridoV.

No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product except the product range mentioned above. 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.

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.
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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.

13. OTHER INFORMATION

For animal treatment only.
Not all package sizes may be marketed.