1. SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Aquavac Saristin 2

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Per dose of 0.05 ml vaccine:

Active substances:

Recombinant protein, IPN, expressed in *E.coli* BL21 (DE3) pLysS pET11d-VP2	0.28 U[1]
Recombinant lipoprotein, SRS, expressed in *E.coli* HMS174 (DE3)/pEGT1/AL-ORF1-90kDa	0.015-0.030 U[1]
Excipients	to 0.05 ml

Adjuvant: Mineral oil

[1]densitometric units

3. PHARMACEUTICAL FORM

Emulsion for injection.

4. CLINICAL PARTICULARS

4.1 Target species

Atlantic salmon (*Salmo Salar* L.), Coho salmon (*Oncorhynchus kisutch* L.), Rainbow trout (*Oncorhynchus mykiss* L.)

4.2 Indications for use, specifying the target species

For active immunisation of Atlantic salmon, Coho salmon and Rainbow trout as an aid in the prevention of infectious pancreatic necrosis and salmonid rickettsial syndrome.

Onset of immunity: 500 degree days for *Piscirickettsia salmonis*, 700 degree days for infectious pancreatic necrosis virus.

4.3 Contraindications

None

4.4 Special warnings

Do not vaccinate sick fish. Do not vaccinate during the smoltification process.

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

i) Special precautions for use in animals

Do not vaccinate fish at water temperatures over 17°C. Do not move vaccinated fish to sea before 700 degree days. Do not vaccinate fish with a weight less than 30 grams.

ii) 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 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.

4.6 Adverse reactions (frequency and seriousness)

Mild, transient adhesions and melanisation of the abdominal cavity may be generated, following vaccination.

4.7 Use in brood stock animals

Do not vaccinate reproductive fish.

4.8 Interaction with other medicinal products and other forms of interaction

Safety and efficacy data are available which support associated use of Aquavac Saristin 4 or its fall-outs with Aquavac ISA when administered at the same time.

After associated use, adverse reactions are similar to those observed when the vaccine is used alone.
Only Speilberg scores of 1 and 2 were very commonly observed.

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

Administer 0.05 ml intra-peritoneally along the central line, approximately 1 pelvic fin length in front of the pelvic fin base.
Shake the bottle well before use without generating air bubbles.

Vaccination is recommended for fish above 30 grams.
Food should be withheld during 1-2 days prior to vaccination. Anesthetize the fish before vaccination. The length and the diameter of the applied needle should be adapted to the actual fish size. Ensure that the recommended dose (0.05 ml) is deposited into the abdominal cavity before the needle is withdrawn.
When administered at the same time with Aquavac ISA, 0.05 ml of each vaccine should be administered using dual injection equipment with both vaccines being administered through a single needle.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

The administration of a double dose has shown to be safe. However, it is not recommended to overdose.

4.11 Withdrawal period (s)
Zero degree days.

5. IMMUNOLOGICAL PROPERTIES
To stimulate active immunity against infectious pancreatic necrosis virus and *Piscirickettsia salmonis*.

6. PHARMACEUTICAL PARTICULARS

6.1 Incompatibilities
Do not dilute, mix or co-administer with any other pharmaceutical product.

6.2 Shelf life
Shelf-life of the veterinary medicinal product as packaged for sale: 24 months.
Once opened, use all the contents of the bottle.

6.3 Special precautions for storage
Store in a refrigerator (2 - 8°C). Do not freeze.

6.4 Nature and composition of immediate packaging
PET bottles closed with a rubber stopper and aluminium cap.
Package size: 250 ml (5000 doses).
Bottles are packed in cardboard boxes (12 bottles per box). Leaflet is included.

6.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from use of such products, if appropriate
Do not keep bottles containing any remaining unused product. To dispose bottles and waste materials, incineration is recommended.

7. MARKETING AUTHORISATION HOLDER
Intervet International B.V.
Wim de Körverstraat
5831 AN Boxmeer
The Netherlands

As represented by the national company

8. MARKETING AUTHORISATION NUMBER(S)

9. DATE OF FIRST AUTHORISATION / RENEWAL OF THE AUTHORISATION

10. DATE OF REVISION OF TEXT

PROHIBITION OF SALE, SUPPLY AND/OR USE
For veterinary use only.

ANNEX A. LABELLING

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

1. NAME OF THE VETERINARY MEDICINAL PRODUCT
Aquavac Saristin 2

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES
Per dose of 0.05 ml:

Active substances:

Recombinant protein, IPN, expressed in *E.coli* BL21 (DE3) pLysS pET11d-VP2	0.28 U[1]
Recombinant lipoprotein, SRS, expressed in *E.coli* HMS174 (DE3)/pEGT1/AL-ORF1-90kDa	0.015-0.030 U[1]
Excipients	to 0.05 ml

Adjuvant: Mineral oil

[1]densitometric units

3. PHARMACEUTICAL FORM
Emulsion for injection

4. PACKAGE SIZE
250 ml (5000 doses)

5. METHOD AND ROUTE(S) OF ADMINISTRATION
Use by i.p. injection - see package leaflet before use

6. EXPIRY DATE
EXP:

7. SPECIAL STORAGE CONDITIONS
Store in a refrigerator
Do not freeze
Once opened, use all the contents of the bottle.

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"
For veterinary use 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, as represented by the national company

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

ANNEX B. PACKAGE LEAFLET

1. NAME OF THE VETERINARY MEDICINAL PRODUCT
Aquavac Saristin 2

2. STATEMENT OF THE ACTIVE SUBSTANCE(S)
Per dose of 0.05 ml vaccine:

Active substances:

Recombinant protein, IPN, expressed in *E.coli* BL21 (DE3) pLysS pET11d-VP2	0.28 U[1]
Recombinant lipoprotein, SRS, expressed in *E.coli* HMS174 (DE3)/pEGT1/AL-ORF1-90kDa	0.015-0.030 U[1]
Excipients	to 0.05 ml
Adjuvant: Mineral oil	

[1]densitometric units

3. PRODUCT OF INTERVET INTERNATIONAL BOXMEER – THE NETHERLANDS

4. INDICATION(S)
For active immunisation of Atlantic salmon, Coho salmon and Rainbow trout as an aid in the prevention of infectious pancreatic necrosis and salmonid rickettsial syndrome.

Onset of immunity: 500 degree days for *Piscirickettsia salmonis*, 700 degree days for infectious pancreatic necrosis virus.

5. CONTRA-INDICATIONS
None

6. ADVERSE REACTIONS
Mild, transient adhesions and melanisation of the abdominal cavity may be generated, following vaccination.

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES
Atlantic salmon (*Salmo Salar* L.), Coho salmon (*Oncorhynchus kisutch* L.), Rainbow trout (*Oncorhynchus mykiss* L.)

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION
Administer 0.05 ml intra-peritoneally along the central line, approximately 1 pelvic fin length in front of the pelvic fin base. The bottle has to be shaken before starting vaccination.

9. ADVICE ON CORRECT ADMINISTRATION
Vaccination is recommended for fish above 30 grams.

Food should be withheld during 1-2 days prior to vaccination. Anesthetize the fish before vaccination. The length and the diameter of the applied needle should be adapted to the actual fish size. Ensure that the recommended dose (0.05 ml) is deposited into the abdominal cavity before the needle is withdrawn.
When administered at the same time with Aquavac ISA, 0.05 ml of each vaccine should be administered using dual injection equipment with both vaccines being administered through a single needle.

Shake the bottle well before use without generating air bubbles.

10. WITHDRAWAL PERIOD

Zero degree days

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight of children.
Store in a refrigerator (2°C – 8°C).
Do not freeze.
Do not use after the expiry date stated on the label.
Once opened, use all the contents of the bottle.

12. SPECIAL WARNINGS, IF NECESSARY

Do not vaccinate sick fish. Do not vaccinate during the smoltification process.

Do not vaccinate fish at water temperatures over 17°C. Do not move vaccinated fish to sea before 700 degree days. Do not vaccinate fish with a weight less than 30 grams.

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 label to the physician.

<u>To the user:</u>
This 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.

Do not vaccinate reproductive fish.

Safety and efficacy data are available which support associated use of Aquavac Saristin 4 or its fall-outs with Aquavac ISA when administered at the same time.

After associated use, adverse reactions are similar to those observed when the vaccine is used alone.
Only Speilberg scores of 1 and 2 were very commonly observed.

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

Do not dilute, mix or co-administer with any other pharmaceutical product.

13. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST REVISED
Date: ……

14. OTHER INFORMATION
For veterinary use only.