ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Porcilis AR-T DF suspension for injection for pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose of 2 ml contains:

Active substances:

- Protein dO (non-toxic deletion derivative of *Pasteurella multocida* dermonecrotic toxin) ≥ 6.2 $\log_2$ TN titre[1]
- Inactivated *Bordetella bronchiseptica* cells ≥ 5.5 $\log_2$ Aggl. titre[2]

[1] Mean toxin neutralising titre obtained after repeated vaccination of a half dose in rabbits.
[2] Mean agglutination titre obtained after a single vaccination of a half dose in rabbits.

Adjuvant:

dl-α-tocopherol acetate 150 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Sodium chloride	
Phosphate buffer	
Simethicone	
Polysorbate 80	
Formaldehyde	≤ 1 mg
Water for injections	

Aqueous, white or nearly white suspension.

3. CLINICAL INFORMATION

3.1 Target species

Pigs (sows and gilts).

3.2 Indications for use for each target species

For the reduction of clinical signs of progressive atrophic rhinitis in piglets by passive oral immunisation with colostrum from dams actively immunised with the vaccine.

3.3 Contraindications

None.

3.4 Special warnings

Vaccinate healthy animals only.

3.5 Special precautions for use

Special precautions for safe use in the target species:
Not applicable.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

Special precautions for the protection of the environment:
Not applicable.

3.6 Adverse events

Pigs (sows and gilts):

Very common (>1 animal / 10 animals treated):	Elevated temperature[1], decreased activity[2], appetite loss[2]; Injection site swelling[3]
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Hypersensitivity reaction (e.g. vomiting, dyspnoea and shock)

[1] Transient; mean increase of 1.5 °C, in some pigs up to 3 °C, could lead to an abortion, and can generally be measured on the day of vaccination or the following day.
[2] On the day of vaccination.
[3] Transient (max diameter: 10 cm) for up to two weeks.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy:
Can be used during pregnancy.

3.8 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.

3.9 Administration routes and dosage

Before use, allow the vaccine to reach room temperature. Shake vigorously before and at intervals during use. Avoid introduction of contamination.

Administer one dose of 2 ml by intramuscular injection to pigs of 18 weeks of age and older. The vaccine should preferably be administered just behind the ear.

Vaccination scheme:

Primary vaccination: inject one dose (2 ml) per pig, followed by a second injection 4 weeks after the first injection. The first injection should be administered 6 weeks before the expected date of farrowing.

Revaccination: a single injection of one dose (2 ml) should be carried out 2 to 4 weeks prior to each subsequent farrowing.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

Apart from a higher average transient increase in body temperature on the day of vaccination or the following day, no adverse reactions other than those mentioned under section 3.6 can be expected following the administration of a double dose of vaccine.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Any person intending to manufacture, import, possess, distribute, sell, supply and use this veterinary medicinal product must first consult the relevant Member State's competent authority on the current vaccination policies, as these activities may be prohibited in a Member State on the whole or part of its territory pursuant to national legislation.

3.12 Withdrawal periods

Zero days.

4. IMMUNOLOGICAL INFORMATION

4.1 ATCvet code: QI09AB04.

To stimulate active immunity in order to provide passive immunity to the progeny against progressive atrophic rhinitis.

Dermonecrotic toxin-producing *Pasteurella multocida* is the pathogen responsible for turbinate atrophy in progressive atrophic rhinitis. Colonisation of the surface of the nasal mucosa by *P. multocida* is most often promoted by *Bordetella bronchiseptica*. The vaccine contains a non-toxic recombinant derivative of the *P. multocida* toxin and inactivated *B. bronchiseptica* cells. The immunogens are incorporated in an adjuvant based on dl-α-tocopherol. Neonatal piglets derive passive immunity via ingestion of colostrum from vaccinated sows/gilts.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 5 years.
Shelf life after first opening the immediate packaging: 10 hours.

5.3 Special precautions for storage

Store in a refrigerator (2 °C – 8 °C).
Do not freeze.

Protect from light.

5.4 Nature and composition of immediate packaging

Glass vial (hydrolytic type I) containing 20 ml or 50 ml, or PET vial containing of 20 ml, 50 ml, 100 ml or 250 ml. The vials are closed with a halogenobutyl rubber stopper and sealed with an aluminium cap.

Pack sizes:
Cardboard box containing one glass vial of 20 ml or 50 ml.
Cardboard box containing one PET vial of 20 ml, 50 ml, 100 ml or 250 ml.

Not all pack sizes may be marketed.

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

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Intervet International B.V.

7. MARKETING AUTHORISATION NUMBER(S)

EU/2/00/026/001
EU/2/00/026/002
EU/2/00/026/003
EU/2/00/026/004
EU/2/00/026/005
EU/2/00/026/006

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 16 November 2000.

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

{MM/YYYY}

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

ANNEX II

OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

None

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARDBOARD BOX with one glass vial of 20 ml or 50 ml
CARDBOARD BOX with one PET vial of 20 ml, 50 ml, 100 ml or 250 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Porcilis AR-T DF suspension for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Per dose of 2 ml:
Protein dO ≥ 6.2 $\log_2$ TN titre
Inac. *B. bronchiseptica* cells ≥ 5.5 $\log_2$ Aggl. titre

3. PACKAGE SIZE

20 ml (10 doses)
50 ml (25 doses)
100 ml (50 doses)
250 ml (125 doses)

4. TARGET SPECIES

Pigs (sows and gilts)

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Intramuscular use.

7. WITHDRAWAL PERIODS

Withdrawal period: zero days.

8. EXPIRY DATE

Exp. {mm/yyyy}
Once broached use within 10 hours.

9. SPECIAL STORAGE PRECAUTIONS

Store in a refrigerator.
Do not freeze.

Protect from light.

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

11. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

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

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Intervet International B.V.

14. MARKETING AUTHORISATION NUMBERS

EU/2/00/026/001
EU/2/00/026/002
EU/2/00/026/003
EU/2/00/026/004
EU/2/00/026/005
EU/2/00/026/006

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

PET VIALS - 100 ml and 250 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Porcilis AR-T DF suspension for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Per dose of 2 ml:
Protein dO ≥ 6.2 $\log_2$ TN titre
Inac. *B. bronchiseptica* cells ≥ 5.5 $\log_2$ Aggl. titre

100 ml (50 doses)
250 ml (125 doses)

3. TARGET SPECIES

Pigs (sows and gilts)

4. ROUTES OF ADMINISTRATION

Intramuscular use.
Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal period: zero days.

6. EXPIRY DATE

Exp. {mm/yyyy}
Once broached use within 10 hours.

7. SPECIAL STORAGE PRECAUTIONS

Store in a refrigerator.
Do not freeze.
Protect from light.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Intervet International B.V.

9. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

GLASS OR PET VIALS – 20 ml and 50 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Porcilis AR-T DF

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Protein dO ≥ 6.2 $\log_2$ TN titre
Inac. *B. bronchiseptica* cells ≥ 5.5 $\log_2$ Aggl. titre

20 ml (10 doses)
50 ml (25 doses)

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}
Once broached use within 10 hours.

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Porcilis AR-T DF suspension for injection for pigs

2. Composition

Each dose of 2 ml contains:

Active substances:

- Protein dO (non-toxic deletion derivative of *Pasteurella multocida* dermonecrotic toxin)	≥ 6.2 $\log_2$ TN titre[1]
- Inactivated *Bordetella bronchiseptica* cells	≥ 5.5 $\log_2$ Aggl. titre[2]

[1] Mean toxin neutralising titre obtained after repeated vaccination of a half dose in rabbits.
[2] Mean agglutination titre obtained after a single vaccination of a half dose in rabbits.

Adjuvant:

dl-α-tocopherol acetate	150 mg

Excipient:

Formaldehyde	≤ 1 mg

Aqueous, white or nearly white suspension.

3. Target species

Pigs (sows and gilts).

4. Indications for use

For the reduction of clinical signs of progressive atrophic rhinitis in piglets by passive oral immunisation with colostrum from dams actively immunised with the vaccine.

5. Contraindications

None.

6. Special warnings

Special warnings:
Vaccinate healthy animals only.

Special precautions for safe use in the target species:
Not applicable.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

Special precautions for the protection of the environment:
Not applicable.

Pregnancy:
Can be used during pregnancy.

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:
Apart from a higher average transient increase in body temperature on the day of vaccination or the following day, no adverse reactions other than those mentioned under section "Adverse events" can be expected following the administration of a double dose of vaccine.

Major incompatibilities:
Do not mix with any other veterinary medicinal product.

7. Adverse events

Pigs (sows and gilts):

Very common (>1 animal / 10 animals treated):	Elevated temperature[1], decreased activity[2], appetite loss[2]; Injection site swelling[3]
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Hypersensitivity reaction (e.g. vomiting, dyspnoea and shock)

[1] Transient; mean increase of 1.5 °C, in some pigs up to 3 °C, could lead to an abortion, and can generally be measured on the day of vaccination or the following day.
[2] On the day of vaccination.
[3] Transient (max diameter: 10 cm) for up to two weeks.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system: {national system details}.

8. Dosage for each species, routes and method of administration

Administer one dose of 2 ml by intramuscular injection to pigs of 18 weeks of age and older. The vaccine should preferably be administered just behind the ear.

Vaccination scheme:

Primary vaccination: inject one dose (2 ml) per pig, followed by a second injection 4 weeks after the first injection. The first injection should be administered 6 weeks before the expected date of farrowing

Revaccination: a single injection of one dose (2 ml) should be carried out 2 to 4 weeks prior to each subsequent farrowing.

9. Advice on correct administration

Before use, allow the vaccine to reach room temperature.
Shake vigorously before use and at intervals during use.
Avoid introduction of contamination.

10. Withdrawal periods

Zero days.

11. Special storage precautions

Keep out of the sight and reach of children.
Store in a refrigerator (2 °C – 8 °C).
Do not freeze.
Protect from light.
Do not use this veterinary medicinal product after the expiry date which is stated on the label. The expiry date refers to the last day of that month.

Shelf life after first opening the immediate packaging: 10 hours.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

EU/2/00/026/001-006

Pack sizes:
Cardboard box containing one glass vial of 20 ml or 50 ml.
Cardboard box containing one PET vial of 20 ml, 50 ml, 100 ml or 250 ml.
Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

{MM/YYYY}

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release and contact details to report suspected adverse reactions:
Intervet International B.V., Wim de Körverstraat 35, 5831 AN Boxmeer, The Netherlands

België/Belgique/Belgien
Tél/Tel: + 32 (0)2 370 94 01

Република България
Тел: + 359 28193749

Česká republika
Tel: + 420 233 010 242

Danmark
Tlf: + 45 44 82 42 00

Deutschland
Tel: + 49 (0)8945614100

Eesti
Tel: + 37052196111

Ελλάδα
Τηλ: + 30 210 989 7452

España
Tel: + 34 923 19 03 45

France
Tél: + 33 (0)241228383

Hrvatska
Tel: + 385 1 6611339

Ireland
Tel: + 353 (0) 1 2970220

Ísland
Sími: + 354 535 7000

Italia
Tel: + 39 02 516861

Κύπρος
Τηλ: + 30 210 989 7452

Latvija
Tel: + 37052196111

Lietuva
Tel: + 37052196111

Luxembourg/Luxemburg
Tél/Tel: + 32 (0)2 370 94 01

Magyarország
Tel.: + 36 1 439 4597

Malta
Tel: + 39 02 516861

Nederland
Tel: + 32 (0)2 370 94 01

Norge
Tlf: + 47 55 54 37 35

Österreich
Tel: + 43 (1) 256 87 87

Polska
Tel.: + 48 22 18 32 200

Portugal
Tel: + 351 214 465 700

România
Tel: + 40 21 311 83 11

Slovenija
Tel: + 385 1 6611339

Slovenská republika
Tel: + 420 233 010 242

Suomi/Finland
Puh/Tel: + 358 10 2310 750

Sverige
Tel: + 46 (0)8 522 216 60

United Kingdom (Northern Ireland)
Tel: + 353 (0) 1 2970220

17. Other information

Dermonecrotic toxin-producing *Pasteurella multocida* is the pathogen responsible for turbinate atrophy in progressive atrophic rhinitis. Colonisation of the surface of the nasal mucosa by *P. multocida* is most often promoted by *Bordetella bronchiseptica*. The vaccine contains a non-toxic recombinant derivative of the *P. multocida* toxin and inactivated *B. bronchiseptica* cells. The immunogens are incorporated in an adjuvant based on dl-α-tocopherol. Neonatal piglets derive passive immunity via ingestion of colostrum from vaccinated sows/gilts.