SPC

Porcilis® AR-T DF

MSD Animal Health

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 log2 TN titre[1]

- Inactivated *Bordetella bronchiseptica* cells
≥5.5 log2 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
For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Suspension for injection.

4. CLINICAL PARTICULARS

4.1 Target species
Pigs (sows and gilts).

4.2 Indications for use, specifying the 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.

4.3 Contraindications
None.

4.4 Special warnings
None.

4.5 Special precautions for use

Special precautions for use in animals
Vaccinate only healthy animals

Special precautions to be taken by the person administering the 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.

4.6 Adverse reactions (frequency and seriousness)
A mean transient increase in body temperature of 1.5 °C, in some pigs up to 3 °C, which could lead to an abortion, can generally be measured on the day of vaccination or the following day. Reduced activity and lack of appetite on the day of vaccination very commonly occurs and/or a transient swelling (max diameter: 10 cm) for up to two weeks may arise at the site of injection. In very rare cases other immediate hypersensitivity reactions, e.g. vomiting, dyspnoea and shock, may occur.

4.7 Use during pregnancy, lactation or lay
Can be used during pregnancy (see details under section 4.9).

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
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.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary
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 4.6 can be expected following the administration of a double dose of vaccine.

4.11 Withdrawal period
Zero days

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: inactivated bacterial vaccine.
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 *Pasteurella multocida* is most often promoted by *Bordetella bronchiseptica*. The vaccine contains a non-toxic recombinant derivative of the Pasteurella multocida toxin and inactivated *Bordetella 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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients
- Sodium chloride
- Phosphate buffer
- Simethicone
- Polysorbate 80
- Formaldehyde
- Water for injections

6.2 Incompatibilities
Do not mix with any other veterinary medicinal product.

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

6.4 Special precautions for storage
Store in a refrigerator (2°C - 8°C).
Protect from light
Do not freeze.

6.5 Nature and composition of immediate packaging
Cardboard box containing one glass vial (Hydrolytic Type I) of 20 ml or 50 ml.
Cardboard box containing one PET vial of 20 ml, 50 ml, 100 ml or 250 ml.
Vials are closed with a halogenobutyl rubber stopper and sealed with an aluminium cap.
Not all pack sizes may be marketed.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBERS

EU/2/00/026/001-006

9. DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 16 November 2000
Date of last renewal: 17 September 2010

10. DATE OF REVISION OF THE TEXT

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency (http://www.ema.europa.eu/).

PROHIBITION OF SALE, SUPPLY AND/OR USE

The import, sale, supply and/or use of Porcilis AR-T DF is or may be prohibited in certain Member States on the whole or part of their territory pursuant to national animal health policy. Any person intending to import, sell, supply and/or use Porcilis AR-T DF must consult the relevant Member State's competent authority on the current vaccination policies prior to the import, sale, supply and/or use.

ANNEX II

A. MANUFACTURER OF THE BIOLOGICAL ACTIVE SUBSTANCE AND MANUFACTURER RESPONSIBLE FOR BATCH RELEASE

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

C. STATEMENT OF THE MRLs

A. MANUFACTURER OF THE BIOLOGICAL ACTIVE SUBSTANCE AND MANUFACTURER RESPONSIBLE FOR BATCH RELEASE

Name and address of the manufacturer of the biological active substances:

Intervet International B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
The NETHERLANDS

Name and address of the manufacturer responsible for batch release:

Intervet International B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
The NETHERLANDS

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

Veterinary medicinal product subject to prescription.

According to Article 71 of Directive 2001/82/EC of the European Parliament and of the Council as amended, a Member State may, in accordance with its national legislation, prohibit the manufacture, import, possession, sale, supply and/or use of immunological veterinary medicinal products on the whole or part of its territory if it is established that:

a) the administration of the product to animals will interfere with the implementation of a national programme for the diagnosis, control or eradication of animal diseases, or will cause difficulties in certifying the absence of contamination in live animals or in foodstuffs or other products obtained from treated animals.

b) the disease to which the product is intended to confer immunity is largely absent from the territory in question.

C. STATEMENT OF THE MRLs

The active substance being a principle of biological origin intended to produce active immunity is not in the scope of Regulation (EC) No 470/2009.
The excipients (including adjuvants) listed in section 6.1 of the SPC are either allowed substances for which table 1 of the annex to Commission Regulation (EU) No 37/2010 indicates that no MRLs are required or considered as not falling within the scope of Regulation (EC) No 470/2009 when used as in this veterinary medicinal product.

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Porcilis AR-T DF suspension for injection for pigs

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Per dose of 2 ml:
≥6.2 log2 TN titre Protein dO (non-toxic deletion derivative of *Pasteurella multocida* dermonecrotic toxin)
≥5.5 log2 Aggl. titre inac. *B. bronchiseptica* cells
150 mg dl-α-tocopherol acetate

3. PHARMACEUTICAL FORM

Suspension for injection

4. PACKAGE SIZE

20 ml (10 doses) Glass vial
50 ml (25 doses) Glass vial
20 ml (10 doses) PET vial
50 ml (25 doses) PET vial
100 ml (50 doses) PET vial
250 ml (125 doses) PET vial

5. TARGET SPECIES

Pigs (sows and gilts)

6. INDICATION(S)

Vaccine against progressive atrophic rhinitis.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

i.m.
Read the package leaflet before use.

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

8. WITHDRAWAL PERIOD

Withdrawal period: zero days.

9. SPECIAL WARNING(S), IF NECESSARY

10. EXPIRY DATE

EXP {month/year}
Once broached, use within 10 hours.

11. SPECIAL STORAGE CONDITIONS

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

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

For animal treatment only - to be supplied only on veterinary prescription.

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

Keep out of the sight reach and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Intervet International B.V.
NL-5831 AN Boxmeer

16. MARKETING AUTHORISATION NUMBER(S)

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

17. MANUFACTURER'S BATCH NUMBER

Lot

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE (100 and 250 ml vials)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Porcilis AR-T DF

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Read the package leaflet before use.

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

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

4. ROUTE(S) OF ADMINISTRATION

i.m.

5. WITHDRAWAL PERIOD

Withdrawal period: Zero days.

6. BATCH NUMBER

Lot

7. EXPIRY DATE

EXP {month/year}
Once broached, use within 10 hours.

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PORCILIS AR-T DF SUSPENSION FOR INJECTION FOR PIGS

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder and manufacturer:
Intervet International B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
The Netherlands

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Porcilis AR-T DF suspension for injection for pigs

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Each dose of 2 ml contains:

Active substances:
- Protein dO (non-toxic deletion derivative of *Pasteurella multocida* dermonecrotic toxin) ≥6.2 log2 TN titre[1]

- Inactivated *Bordetella bronchiseptica* cells. ≥5.5 log2 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

4. INDICATION(S)

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. ADVERSE REACTIONS

A mean transient increase in body temperature of 1.5°C, in some pigs up to 3 °C, which could lead to an abortion, can generally be measured on the day of vaccination or the following day. Reduced activity and lack of appetite on the day of vaccination very commonly occurs and/or a transient swelling (maxdiameter: 10 cm) for up to two weeks may arise at the site of injection. In very rare cases other immediate hypersensitivity reactions, e.g. vomiting, dyspnoea and shock, may occur.
If you notice any serious effects or other effects not mentioned in this package leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Pigs (sows and gilts).

8. DOSAGE FOR EACH SPECIES, ROUTE(S) 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 PERIOD

Zero 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.
Protect from light.
Do not use after the expiry date stated on the label.
Shelf life after first opening the vial: 10 hours.

12. SPECIAL WARNING(S)

Special precautions for use in animals
Vaccinate only healthy animals.

Special precautions to be taken by the person administering the 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.
Use during pregnancy, lactation or lay
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.

Incompatibilities
Do not mix with any other veterinary medicinal products.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

Detailed information on this product is available on the website of the European Medicines Agency (http://www.ema.europa.eu/).

15. 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 *Pasteurella multocida* is most often promoted by *Bordetella bronchiseptica*. The vaccine contains a non-toxic recombinant derivative of the *Pasteurella multocida* toxin and inactivated *Bordetella 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.

Cardboard box containing one glass vial (Hydrolytic Type I) of 20 ml or 50 ml.
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