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* dermonecrotictoxin)
≥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.

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 ORWASTE MATERIALS, IF ANY

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS ORRESTRICTIONS 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

MSD Animal Health UK Ltd.
Walton Manor, Walton
Milton Keynes
MK7 7AJ

16. MARKETING AUTHORISATION NUMBER(S)

Vm 01708/5052

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 suspension for injection for pigs

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Per dose of 2 ml:
≥6.2 log2 TN titre Protein dO
≥5.5 log2 Aggl. titre inactivated *B. bronchiseptica* cells

dl-α-tocopherol acetate

3. PHARMACEUTICAL FORM

Suspension for injection

4. PACKAGE SIZE

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

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.

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 ORWASTE MATERIALS, IF ANY

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

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 and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

MSD Animal Health UK Ltd.
Walton Manor, Walton
Milton Keynes
MK7 7AJ

16. MARKETING AUTHORISATION NUMBER(S)

Vm 01708/5052

17. MANUFACTURER'S BATCH NUMBER

Lot

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

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

PACKAGE LEAFLET

Porcilis AR-T DF suspension for injection for pigs

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

Marketing authorisation holder and manufacturer:
MSD Animal Health UK Ltd.
Walton Manor, Walton
Milton Keynes
Buckinghamshire
MK7 7AJ

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 *Pasteurellamultocida* 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 andlack 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.

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 thefirst 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 thelabel 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 otherveterinary 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 WASTEMATERIALS, 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 *Pasteurellamultocida* 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.
Cardboard box containing one PET vial of 20 ml, 50 ml, 100 ml or 250 ml.

Not all pack sizes may be marketed.

Approved: 06 April 2022