Issued: April 2022
AN: 02836/2021

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 firstinjection. 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 thefollowing 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 inprogressive 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 passiveimmunity 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

MSD Animal Health UK Limited
Walton Manor, Walton
Milton Keynes
Buckinghamshire
MK7 7AJ

8. MARKETING AUTHORISATION NUMBER

Vm 01708/5052

9. DATE OF THE FIRST AUTHORISATION

16 November 2000

10. DATE OF REVISION OF THE TEXT

April 2022

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.

Approved: 06 April 2022