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

Excipient:

Formaldehyde	≤ 1 mg

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Suspension for injection.
Aqueous, white or nearly white suspension.

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 for each target species

Vaccinate healthy animals only.

4.5 Special precautions for use

Special precautions for use in animals:
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.

4.6 Adverse reactions (frequency and seriousness)

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[4]

[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.
[4] e.g. vomiting, dyspnoea and shock, may occur.

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.

4.7 Use during pregnancy, lactation or lay

Pregnancy:
Can be used during pregnancy.

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 Amount(s) 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(s)

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 *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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium chloride
Phosphate buffer
Simethicone
Polysorbate 80
Water for injections

6.2 Major 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 immediate packaging: 10 hours.

6.4 Special precautions for storage

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

6.5 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.

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

Medicines should not be disposed of via wastewater.

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 FIRST AUTHORISATION

16 November 2000

10. DATE OF REVISION OF THE TEXT

May 2024

PROHIBITION OF SALE, SUPPLY AND/OR USE

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

11. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

Gavin Hall

Approved 23 November 2024