SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Porcilis ColiClos suspension for injection for pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose of 2 ml contains:

Active substances:
Escherichia coli components:

- F4ab fimbrial adhesin	≥ 9.7 $\log_2$ Ab titre[1]
- F4ac fimbrial adhesin	≥ 8.1 $\log_2$ Ab titre[1]
- F5 fimbrial adhesin	≥ 8.4 $\log_2$ Ab titre[1]
- F6 fimbrial adhesin	≥ 7.8 $\log_2$ Ab titre[1]
- LT toxoid	≥ 10.9 $\log_2$ Ab titre[1]

Clostridium perfringens component:

- Type C (strain 578) beta toxoid	≥ 20 IU[2]

[1] Mean antibody titre (Ab) obtained after vaccination of mice with a 1/20 or 1/40 sow dose
[2] International units of beta antitoxin according to Ph. Eur.

Adjuvant:

dl-α-tocopheryl acetate	150 mg

For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Suspension for injection.
Aqueous, white to 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 passive immunisation of progeny by active immunisation of sows and gilts to reduce mortality and clinical signs during the first days of life, caused by those *E. coli* strains, which express the adhesins F4ab (K88ab), F4ac (K88ac), F5 (K99) or F6 (987P) and caused by *C. perfringens* type C.

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:
Protection of piglets is achieved by colostrum intake. Therefore, care should be taken to ensure that each piglet ingests a sufficient quantity of colostrum.

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.

4.6 Adverse reactions (frequency and seriousness)

Pigs (sows and gilts):

Very common (>1 animal / 10 animals treated):	Elevated temperature[1], Injection site swelling[2].
Common (1 to 10 animals in 100 animals):	Decreased activity[3], Appetite loss[3].
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Hypersensitivity reaction.

[1] Up to 2 °C on the day of vaccination.
[2] Sometimes painful and hard up to 10 cm in diameter for up to 25 days.
[3] On the day of vaccination.

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 also section “Contact details” of the package leaflet.

4.7 Use during pregnancy, lactation or lay

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

Intramuscular use.
Administer 1 dose (2 ml) of vaccine per animal in the neck in the area behind the ear.

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

Vaccination scheme:
Primary vaccination: Sows/gilts which have not yet been vaccinated with the product are given a primary injection 6 to 8 weeks before the expected date of farrowing and a second injection 4 weeks later.
Revaccination: A single revaccination is carried out 2 to 4 weeks before the expected date of farrowing.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

A slight redness and/or roughness may transiently occur after a double dose vaccination. No adverse reactions other than those mentioned in section 4.6 have been observed.

4.11 Withdrawal period(s)

Zero days.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Immunologicals for *Suidae*, inactivated bacterial vaccine.
ATCvet code: QI09AB08.

To stimulate active immunity in order to provide passive immunity to the progeny against enterotoxicosis caused by *E. coli* expressing fimbrial adhesins F4ab (K88ab), F4ac (K88ac), F5 (K99), F6 (987P) and against (necrotic) enteritis caused by *C. perfringens* type C. Vaccination results in an antibody response with neutralising activity against LT toxin.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Polysorbate 80
Simethicone
Sodium chloride
Potassium chloride
Potassium dihydrogen phosphate
Disodium hydrogen phosphate
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: 2 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

Cardboard box with PET vial of 20 ml, 50 ml, 100 ml, 200 ml or 250 ml.
Cardboard box with type I glass vial 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.
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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product 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 01708/5053

9. DATE OF FIRST AUTHORISATION

14 June 2012

10. DATE OF REVISION OF THE TEXT

July 2023

11. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Approved 09 February 2024