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

Clostridium perfringens component:
- *Clostridium perfringens* type C (strain CN 883) 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

Excipients:

Qualitative composition of excipients and other constituents
Polysorbate 80
Simethicone
Sodium chloride
Potassium chloride
Potassium dihydrogen phosphate
Disodium hydrogen phosphate
Water for injections

Aqueous, white to nearly white suspension.

3. CLINICAL INFORMATION

3.1 Target species

Pigs (sows and gilts).

3.2 Indications for use for each 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.

3.3 Contraindications

None.

3.4 Special warnings

Vaccinate healthy animals only.

3.5 Special precautions for use

Special precautions for safe use in the target species:
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.

3.6 Adverse events

Pigs (sows and gilts):

Very common (>1 animal / 10 animals treated):	Elevated temperature[1], Injection site swelling[2].
Common (1 to 10 animals / 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 the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy:
Can be used during pregnancy.

3.8 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.

3.9 Administration routes and dosage

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.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

A slight redness and/or roughness may transiently occur after a double dose vaccination. No adverse reactions other than those mentioned in section 3.6 have been observed.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Zero days.

4. IMMUNOLOGICAL INFORMATION

4.1 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.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product.

5.2 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.

5.3 Special precautions for storage

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

5.4 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.

5.5 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.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

MSD Animal Health UK Limited

7. MARKETING AUTHORISATION NUMBER

Vm 01708/5053

8. DATE OF FIRST AUTHORISATION

14 June 2012

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

April 2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

Gavin Hall
Approved: 16 June 2025