PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box with a vial of 20, 50, 100, 200 or 250 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Porcilis ColiClos suspension for injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Per dose of 2 ml:

E. coli: F4ab fimbrial adhesin	≥ 9.7 $\log_2$ Ab titre
F4ac fimbrial adhesin	≥ 8.1 $\log_2$ Ab titre
F5 fimbrial adhesin	≥ 8.4 $\log_2$ Ab titre
F6 fimbrial adhesin	≥ 7.8 $\log_2$ Ab titre
LT toxoid	≥ 10.9 $\log_2$ Ab titre
C. perfringens type C beta toxoid	≥ 20 IU

3. PACKAGE SIZE

20 ml
50 ml
100 ml
200 ml
250 ml

4. TARGET SPECIES

Pigs (sows and gilts)

5. INDICATION(S)

6. ROUTES OF ADMINISTRATION

Intramuscular use.

7. WITHDRAWAL PERIODS

Withdrawal period: Zero days

8. EXPIRY DATE

Exp. {mm/yyyy}
Once broached use within 10 hours.

9. SPECIAL STORAGE PRECAUTIONS

Store in a refrigerator.
Do not freeze.
Protect from light.

Keep the vial in the outer box.

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

11. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

12. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

13. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

14. MARKETING AUTHORISATION NUMBERS

Vm 01708/5053

15. BATCH NUMBER

Lot {number}

16. SPECIAL WARNING(S), IF NECESSARY

17. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: Read the package leaflet.

18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

POM-V To be supplied only on veterinary prescription.

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

GLASS or PET VIAL LABEL (100, 200 and 250 ml)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Porcilis ColiClos suspension for injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Per dose of 2 ml:

E. coli:	F4ab fimbrial adhesin	≥ 9.7 $\log_2$ Ab titre
	F4ac fimbrial adhesin	≥ 8.1 $\log_2$ Ab titre
	F5 fimbrial adhesin	≥ 8.4 $\log_2$ Ab titre
	F6 fimbrial adhesin	≥ 7.8 $\log_2$ Ab titre
	LT toxoid	≥ 10.9 $\log_2$ Ab titre
C. perfringens type C beta toxoid		≥ 20 IU

3. TARGET SPECIES

Pigs (sows and gilts).

4. ROUTES OF ADMINISTRATION

Intramuscular use.
Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal period: Zero days.

6. EXPIRY DATE

Exp. {mm/yyyy}
Once broached use within 10 hours.

7. SPECIAL STORAGE PRECAUTIONS

Store in a refrigerator.
Do not freeze.
Protect from light.
Keep the vial in the outer box.

8. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

9. BATCH NUMBER

Lot {number}

10. PACKAGE SIZE

100 ml
200 ml
250 ml

11. INDICATION(S)

12. SPECIAL WARNING(S), IF NECESSARY

13. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: Read package leaflet.

14. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

For animal treatment only.
POM-V To be supplied only on veterinary prescription.

15. MARKETING AUTHORISATION NUMBER(S)

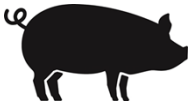
Vm 01708/5053

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

GLASS or PET VIAL LABEL (20, 50 ml)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Porcilis ColiClos



2. QUALITATIVE AND QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCE(S)

E. coli: fimbrial adhesins, LT toxoid
C. perfringens beta toxoid

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}
Once broached use within 10 hours.

5. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

20 ml
50 ml

6. ROUTE(S) OF ADMINISTRATION

IM use.

7. WITHDRAWAL PERIOD

Withdrawal period: Zero days.

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Porcilis ColiClos suspension for injection for pigs

2. 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

Aqueous, white to nearly white suspension.

3. TARGET SPECIES

Pigs (sows and gilts).

4. INDICATIONS FOR USE

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.

5. CONTRAINDICATIONS

None.

6. SPECIAL WARNING(S)

For animal treatment only.

Special precautions for use in animals:
Vaccinate healthy animals only.
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.

Pregnancy:
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 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.

Overdose:
A slight redness and/or roughness may transiently occur after a double dose vaccination. No adverse events other than those mentioned in section “Adverse events” have been observed.

Major incompatibilities:
Do not mix with any other veterinary medicinal product.

7. 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 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 product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first

instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system:
Email: adverse.events@vmd.gov.uk
Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

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

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.

9. ADVICE ON CORRECT ADMINISTRATION

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

10. WITHDRAWAL PERIOD(S)

Zero days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Keep the vial in the outer box.

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

Do not use this veterinary medicinal product after the expiry date which is stated on the carton and vial label after Exp. The expiry date refers to the last day of that month.

Shelf life after first opening the immediate packaging: 10 hours.

12. SPECIAL PRECAUTIONS FOR DISPOSAL

Medicines should not be disposed of via wastewater.

Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

13. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 01708/5053

Pack sizes:
Cardboard box with a glass vial of 20, 50, 100 or 250 ml.
Cardboard box with a PET vial of 20, 50, 100, 200 or 250 ml.

Not all pack sizes may be marketed.

15. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST REVISED

July 2023

Find more product information by searching for the ‘Product Information Database’ or ‘PID’ on www.gov.uk.

16. CONTACT DETAILS

Marketing authorisation holder and contact details to report suspected adverse reactions:
MSD Animal Health UK Ltd.
Walton Manor, Walton
Milton Keynes
Buckinghamshire
MK7 7AJ, UK
Tel.: +44 (0)1908 685685

Manufacturer responsible for batch release:
Intervet International B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
The Netherlands

17. OTHER INFORMATION

Immunological properties of the product: 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.

POM-V To be supplied only on veterinary prescription.

Approved 09 February 2024