Issued: April 2022
AN: 02836/2021

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.

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)

In laboratory studies and field trials:
An increase in body temperature up to 2°C was very commonly observed on the day of vaccination. Reduced activity and lack of appetite on the day of vaccination commonly occurred and/or a sometimes painful and hard swelling up to 10 cm diameter for up to 25 days were very commonly observed at the site of injection.

In post marketing experience:
Hypersensitivity reactions may occur in very rare cases.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

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 Amounts 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.
ATC vet 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 neutralizing activity against LT toxin.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium chloride
Potassium chloride
Disodium hydrogen phosphate
Potassium dihydrogen phosphate
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: 2 years
Shelf life after first opening the vial: 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 products 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

April 2022

Approved: 06 April 2022