SPC

Porcilis® ColiClos

MSD Animal Health

ANNEX I

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 log2 Ab titre[1]
- F4ac fimbrial adhesin ≥ 8.1 log2 Ab titre[1]
- F5 fimbrial adhesin ≥ 8.4 log2 Ab titre[1]
- F6 fimbrial adhesin ≥ 7.8 log2 Ab titre[1]
- LT toxoid ≥ 10.9 log2 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

Excipient:
Formaldehyde ≤1 mg
For a 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 entero-toxicosis 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

Intervet International B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
The Netherlands

8. MARKETING AUTHORISATION NUMBER(S)

EU/2/12/141/001-009

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 14/06/2012
Date of last renewal: 29/03/2017

10. DATE OF REVISION OF THE TEXT

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency (http://www.ema.europa.eu/).

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.

ANNEX II

A. MANUFACTURERS OF THE BIOLOGICAL ACTIVE SUBSTANCES AND MANUFACTURER RESPONSIBLE FOR BATCH RELEASE

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

C. STATEMENT OF THE MRLs

A. MANUFACTURERS OF THE BIOLOGICAL ACTIVE SUBSTANCES AND MANUFACTURER RESPONSIBLE FOR BATCH RELEASE

Name and address of the manufacturers of the biological active substances
Intervet International B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
The Netherlands

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

Name and address of the manufacturers responsible for batch release

Intervet International B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
The Netherlands

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

The printed package leaflet of the medicinal product must state the name and address of the manufacturer responsible for the release of the concerned batch.

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

Veterinary medicinal product subject to prescription.

C. STATEMENT OF THE MRLs

The active substances being a principle of biological origin intended to produce passive immunity are not within the scope of Regulation (EC) No 470/2009.

The excipients (including adjuvants) listed in section 6.1 of the SPC are allowed substances for which table 1 of the annex to Commission Regulation (EU) No 37/2010 indicates that no MRLs are required or are considered as not falling within the scope of Regulation (EC) No 470/2009 when used as in this veterinary medicinal product.

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE
BOX 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 for pigs

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Per dose of 2 ml:
E. coli:
F4ab fimb. adhe. ≥ 9.7 $\log_2$ Ab titre
F4ac fimb. adhe. ≥ 8.1 $\log_2$ Ab titre
F5 fimb. adhe. ≥ 8.4 $\log_2$ Ab titre
F6 fimb. adhe. ≥ 7.8 $\log_2$ Ab titre
LT toxoid ≥ 10.9 $\log_2$ Ab titre

C. perfringens type C toxoid ≥ 20 IU
dl-α-tocopheryl acetate

3. PHARMACEUTICAL FORM

Suspension for injection

4. PACKAGE SIZE

20 ml (10 doses)
50 ml (25 doses)
100 ml (50 doses)
200 ml (100 doses)
250 ml (125 doses)

5. TARGET SPECIES

Pigs (sows and gilts)

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Intramuscular use.
Read the package leaflet before use.

PARTICULARS TO APPEAR ON THE OUTER PACKAGE
BOX Cardboard box with a vial of 20, 50, 100, 200 or 250 ml

8. WITHDRAWAL PERIOD

Withdrawal period: zero days.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Once broached, use within 10 hours.

11. SPECIAL STORAGE CONDITIONS

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

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read the package leaflet.

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

For animal treatment only. To be supplied only on veterinary prescription.

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

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Intervet International B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
The Netherlands

16. MARKETING AUTHORISATION NUMBER(S)

EU/2/00/026/001
EU/2/00/026/002
EU/2/00/026/003
EU/2/00/026/004

17. MANUFACTURER'S BATCH NUMBER

Lot

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE VIAL LABEL 100, 200 and 250 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Porcilis ColiClos suspension for injection for pigs

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Per dose of 2 ml:
E. coli:
F4ab fimb. adhe. ≥ 9.7 $\log_2$ Ab titre
F4ac fimb. adhe. ≥ 8.1 $\log_2$ Ab titre
F5 fimb. adhe. ≥ 8.4 $\log_2$ Ab titre
F6 fimb. adhe. ≥ 7.8 $\log_2$ Ab titre
LT toxoid ≥ 10.9 $\log_2$ Ab titre

C. perfringens type C toxoid ≥ 20 IU

3. PHARMACEUTICAL FORM

Suspension for injection

4. PACKAGE SIZE

100 ml (50 doses)
200 ml (100 doses)
250 ml (125 doses)

5. TARGET SPECIES

Pigs (sows and gilts)

6. INDICATION(S)

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE
VIAL LABEL 100, 200 and 250 ml

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Intramuscular use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Withdrawal period: zero days.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Once broached, use within 10 hours.

11. SPECIAL STORAGE CONDITIONS

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

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

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

For animal treatment only. To be supplied only on veterinary prescription.

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

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Intervet International B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
The Netherlands

16. MARKETING AUTHORISATION NUMBER(S)

17. MANUFACTURER'S BATCH NUMBER

Lot

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS
VIAL LABEL 20, 50 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Porcilis ColiClos suspension for injection

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

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

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

20 ml (10 doses)
50 ml (25 doses)

4. ROUTE(S) OF ADMINISTRATION

IM

5. WITHDRAWAL PERIOD

Withdrawal period: Zero days.

6. BATCH NUMBER

Lot

7. EXPIRY DATE

EXP {month/year}
Once broached, use within 10 hours.

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PORCILIS COLICLOS SUSPENSION FOR INJECTION FOR PIGS

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder and manufacturer:
Intervet International B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
The Netherlands

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

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Porcilis ColiClos suspension for injection for pigs

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

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 IU2

[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 for injection.
Formaldehyde ≤1 mg

4. INDICATION(S)

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.

5. CONTRAINDICATIONS

None.

6. ADVERSE REACTIONS

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).

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 inform your veterinary surgeon.

7. TARGET SPECIES

Pigs (sows and gilts)

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.
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 label.
Shelf life after first opening the container: 10 hours.

12. SPECIAL WARNING(S)

Special warnings for each target species:
Vaccinate healthy animals only.

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.

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 (symptoms, emergency procedures, antidotes):
A slight redness and/or roughness may transiently occur after a double dose vaccination. No adverse reactions other than those mentioned in section “Adverse Reactions” have been observed.

Incompatibilities:
Do not mix with any other veterinary medicinal product.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency (http://www.ema.europa.eu/).

15. OTHER INFORMATION

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.

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 neutralizing activity against LT toxin.