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:
- *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.

Adjuvants:
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.

Special precautions for the protection of the environment:

Not applicable.

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 treated)	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 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.

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 a PET vial of 20 ml, 50 ml, 100 ml, 200 ml or 250 ml.
Cardboard box with a 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 products or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste.

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

Intervet International B.V.

7. MARKETING AUTHORISATION NUMBER(S)

EU/2/12/141/001
EU/2/12/141/002
EU/2/12/141/003
EU/2/12/141/004
EU/2/12/141/005
EU/2/12/141/006
EU/2/12/141/007
EU/2/12/141/008
EU/2/12/141/009

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 14/06/2012

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

{MM/YYYY}

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

ANNEX II

OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

None.

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

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

4. TARGET SPECIES

Pigs (sows and gilts)

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Intramuscular use.

7. WITHDRAWAL PERIODS

Withdrawal periods: 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.

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 OF THE MARKETING AUTHORISATION HOLDER

Intervet International B.V.

14. MARKETING AUTHORISATION NUMBERS

EU/2/12/141/001 (1 x 20 ml PET vial)
EU/2/12/141/002 (1 x 50 ml PET vial)
EU/2/12/141/003 (1 x 100 ml PET vial)
EU/2/12/141/004 (1 x 200 ml PET vial)
EU/2/12/141/005 (1 x 250 ml PET vial)
EU/2/12/141/006 (1 x 20 ml glass vial)
EU/2/12/141/007 (1 x 50 ml glass vial)
EU/2/12/141/008 (1 x 100 ml glass vial
EU/2/12/141/009 (1 x 250 ml glass vial)

15. BATCH NUMBER

Lot {number}

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 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

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

3. TARGET SPECIES

Pigs (sows and gilts)

4. ROUTES OF ADMINISTRATION

Intramuscular use.
Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal periods: 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.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Intervet International B.V.

9. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

GLASS and PET VIAL LABEL (20, 50 ml)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Porcilis ColiClos

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

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

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

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

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

B. PACKAGE LEAFLET

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:
- *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.

Adjuvants:
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 warnings

Special precautions for safe use in the target species:

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 / 100 animals treated):
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: {national system details}.

8. Dosage for each species, routes 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 periods

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 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 or household waste.

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 applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

EU/2/12/141/001-009.

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

{MM/YYYY}

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary) .

16. Contact details

Marketing authorisation holder, manufacturer responsible for batch release and contact details to report suspected adverse events:

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

België/Belgique/Belgien
Tél/Tel: + 32 (0)2 370 94 01

Република България
Тел: + 359 28193749

Česká republika
Tel: + 420 233 010 242

Danmark
Tlf: + 45 44 82 42 00

Deutschland
Tel: + 49 (0)8945614100

Eesti
Tel: + 37052196111

Ελλάδα
Τηλ: + 30 210 989 7452

España
Tel: + 34 923 19 03 45

France
Tél: + 33 (0)241228383

Hrvatska
Tel: + 385 1 6611339

Ireland
Tel: + 353 (0) 1 2970220

Ísland
Sími: + 354 535 7000

Italia
Tel: + 39 02 516861

Lietuva
Tel: + 37052196111

Luxembourg/Luxemburg
Tél/Tel: + 32 (0)2 370 94 01

Magyarország
Tel.: + 36 1 439 4597

Malta
Tel: + 39 02 516861

Nederland
Tel: + 32 (0)2 370 94 01

Norge
Tlf: + 47 55 54 37 35

Österreich
Tel: + 43 (1) 256 87 87

Polska
Tel.: + 48 22 18 32 200

Portugal
Tel: + 351 214 465 700

România
Tel: + 40 21 311 83 11

Slovenija
Tel: + 385 1 6611339

Slovenská republika
Tel: + 420 233 010 242

Suomi/Finland
Puh/Tel: + 358 10 2310 750

Κύπρος
Τηλ: + 30 210 989 7452

Latvija
Tel: + 37052196111

Sverige
Tel: + 46 (0)8 522 216 60

United Kingdom (Northern Ireland)
Tel: + 353 (0) 1 2970220

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 neutralizing activity against LT toxin.