ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Porcilis Porcoli Diluvac Forte 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 ≥ 9.0 $\log_2$ Ab titre[1]
- *Escherichia coli*, fimbrial adhesin F4ac ≥ 5.4 $\log_2$ Ab titre[1]
- *Escherichia coli*, fimbrial adhesin F5 ≥ 6.8 $\log_2$ Ab titre[1]
- *Escherichia coli*, fimbrial adhesin F6 ≥ 7.1 $\log_2$ Ab titre[1]
- *Escherichia coli*, LT toxoid ≥ 6.8 $\log_2$ Ab titre[1]

[1] Mean antibody titre (Ab) obtained after vaccination of mice with a 1/20 sow dose.

Adjuvants:
dl-α-tocopherol acetate 150 mg

Excipients:

Qualitative composition of excipients and other constituents
Polysorbate 80
Potassium chloride
Potassium dihydrogen phosphate
Simethicone emulsion
Sodium chloride
Disodium phosphate dihydrate
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 piglets by active immunisation of sows/gilts to reduce mortality and clinical signs such as diarrhoea due to neonatal enterotoxicosis during the first days of life, caused by those *E.coli* strains, which express the fimbrial adhesins F4ab (K88ab), F4ac (K88ac), F5 (K99) or F6 (987P).

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:

Not applicable.

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], Listless[2], Reduced food intake[2]; Injection site reaction[3]

[1] Up to 3 °C, for up to 1 day after vaccination.
[2] For up to 3 days after vaccination.
[3] Recedes within 14 days, may occasionally exceed a diameter of 5 cm.

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. It is therefore recommended that no other vaccine should be administered within 14 days before or after vaccination with this 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

Before using the vaccine allow it to reach room temperature (15-25 °C) and shake well before use.
Use sterile syringes and needles. Avoid introduction of contamination.

Intramuscular use.
Administer one dose (2 ml) per animal by intramuscular injection in the neck in the area behind the ear of sows/gilts.

Vaccination scheme:

Basic vaccination: Sows/gilts which have not yet been vaccinated with the product shall be given an injection preferably 6 to 8 weeks before the expected date of farrowing followed by a second injection 4 weeks later.

Revaccination: A single revaccination shall be carried out during the second half of each subsequent pregnancy, preferably 2 to 4 weeks before the expected date of farrowing.

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

No undesirable effects other than those observed and mentioned in the "Adverse events" section 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: QI09AB02

The fimbrial adhesins F4ab, F4ac, F5, and F6 are responsible for the adhesion and the virulence of *E.coli* strains, which cause neonatal enterotoxicosis in piglets. These immunogens are incorporated in an adjuvant in order to enhance a prolonged stimulation of immunity. Neonatal piglets derive passive immunity via ingestion of colostrum from vaccinated sows/gilts.

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: 3 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 1 glass (hydrolytic type I) or 1 PET vial of 20, 50 or 100 ml with a halogenobutyl rubber stopper and a coded 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/2/96/001/003-008

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 29/02/1996.

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

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Porcilis Porcoli Diluvac Forte suspension for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Per dose of 2 ml:

E. coli: F4ab fimbrial adhesin	≥ 9.0 $\log_2$ Ab titre
F4ac fimbrial adhesin	≥ 5.4 $\log_2$ Ab titre
F5 fimbrial adhesin	≥ 6.8 $\log_2$ Ab titre
F6 fimbrial adhesin	≥ 7.1 $\log_2$ Ab titre
LT toxoid	≥ 6.8 $\log_2$ Ab titre

3. PACKAGE SIZE

20 ml (10 doses)
50 ml (25 doses)
100 ml (50 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 3 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/2/96/001/003 (20 ml glass vial)
EU/2/96/001/006 (20 ml PET vial)
EU/2/96/001/004 (50 ml glass vial)
EU/2/96/001/007 (50 ml PET vial)
EU/2/96/001/005 (100 ml glass vial)
EU/2/96/001/008 (100 ml PET vial)

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

GLASS or PET VIAL LABEL (100 ml)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Porcilis Porcoli Diluvac Forte suspension for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Per dose of 2 ml:

E. coli: F4ab fimbrial adhesin	≥ 9.0 $\log_2$ Ab titre
F4ac fimbrial adhesin	≥ 5.4 $\log_2$ Ab titre
F5 fimbrial adhesin	≥ 6.8 $\log_2$ Ab titre
F6 fimbrial adhesin	≥ 7.1 $\log_2$ Ab titre
LT toxoid	≥ 6.8 $\log_2$ Ab titre

100 ml (50 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 3 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 or PET VIAL LABEL (20, 50 ml)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Porcilis Porcoli DF

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

E.coli: fimbrial adhesins, LT toxoid

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

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}
Once broached use within 3 hours.

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Porcilis Porcoli Diluvac Forte suspension for injection for pigs

2. Composition

Each dose of 2 ml contains:

Active substances:
Escherichia coli components:
- *Escherichia coli*, fimbrial adhesin F4ab ≥ 9.0 $\log_2$ Ab titre[1]
- *Escherichia coli*, fimbrial adhesin F4ac ≥ 5.4 $\log_2$ Ab titre[1]
- *Escherichia coli*, fimbrial adhesin F5 ≥ 6.8 $\log_2$ Ab titre[1]
- *Escherichia coli*, fimbrial adhesin F6 ≥ 7.1 $\log_2$ Ab titre[1]
- *Escherichia coli*, LT toxoid ≥ 6.8 $\log_2$ Ab titre[1]

[1] Mean antibody titre (Ab) obtained after vaccination of mice with a 1/20 sow dose.

Adjuvants:
dl-α-tocopherol 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 piglets by active immunisation of sows/gilts to reduce mortality and clinical signs such as diarrhoea due to neonatal enterotoxicosis during the first days of life, caused by those *E.coli* strains, which express the fimbrial adhesins F4ab (K88ab), F4ac (K88ac), F5 (K99) or F6 (987P).

5. Contraindications

None.

6. Special warnings

Special warnings:
Vaccinate healthy animals only.

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. It is therefore recommended that no other vaccine should be administered within 14 days before or after vaccination with this 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:
No undesirable effects other than those observed and mentioned in the "Adverse events" section 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], Listless[2], Reduced food intake[2]; Injection site reaction[3]

[1] Up to 3 °C, for up to 1 day after vaccination.
[2] For up to 3 days after vaccination.
[3] Recedes within 14 days, may occasionally exceed a diameter of 5 cm.

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 one dose (2 ml) per animal by intramuscular injection in the neck in the area behind the ear to sows/gilts.

Vaccination scheme:
Basic vaccination: Sows/gilts which have not yet been vaccinated with the product shall be given an injection preferably 6 to 8 weeks before the expected date of farrowing followed by a second injection 4 weeks later.
Revaccination: A single revaccination shall be carried out during the second half of each subsequent pregnancy, preferably 2 to 4 weeks before the expected date of farrowing.

9. Advice on correct administration

Before using the vaccine allow it to reach room temperature (15-25 °C) and shake well before use.
Use sterile syringes and needles. Avoid introduction of contamination.

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 label after Exp. The expiry date refers to the last day of that month.

Shelf life after first opening the immediate packaging: 3 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.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

EU/2/96/001/003-008

Cardboard box with 1 glass or 1 PET vial of 20, 50 or 100 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

Lietuva
Tel: + 37052196111

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

Κύπρος
Τηλ: + 30 210 989 7452

Latvija
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

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

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

17. Other information

Vaccine to stimulate active immunity of sows/gilts in order to provide passive immunity to their progeny against *E. coli* strains that express the fimbrial adhesins F4ab, F4ac, F5 and F6.
The fimbrial adhesins F4ab, F4ac, F5, and F6 are responsible for the adhesion and the virulence of *E.coli* strains, which cause neonatal enterotoxicosis in piglets. These immunogens are incorporated in an adjuvant in order to enhance a prolonged stimulation of immunity. Neonatal piglets derive passive immunity via ingestion of colostrum from vaccinated sows/gilts.