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).