1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Porcilis Porcoli **Diluvac Forte**

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Per dose of two ml:

Active substances:

- F4ab (K88ab) fimbrial adhesin	≥ 9.0 $\log_2$ Ab titre[1]
- F4ac (K88ac) fimbrial adhesin	≥ 5.4 $\log_2$ Ab titre[1]
- F5 (K99) fimbrial adhesin	≥ 6.8 $\log_2$ Ab titre[1]
- F6 (987P) fimbrial adhesin	≥ 7.1 $\log_2$ Ab titre[1]
- 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.

Adjuvant:

dl-α-tocopherol acetate	150 mg

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Suspension for injection.

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 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).

4.3 Contraindications

None

4.4 Special warnings

None

4.5 Special precautions for use

Special precautions for use in animals

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.
Vaccinate only healthy animals.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

In the case of accidental self-injection, seek medical advice immediately and show the package leaflet or label to the physician.

4.6 Adverse reactions (frequency and seriousness)

A mean transient increase in body temperature of about 1°C, in some pigs up to 3°C, may occur in the first 24 hours after vaccination. Reduced feed intake and listlessness may occur in approximately 10% of the animals on the day of vaccination, but returns to normal within 1-3 days. A transient swelling and redness at the injection site may be observed in approximately 5% of the animals. The diameter of the swelling is in general below 5 cm, but in some cases a larger swelling may occur. Swelling and redness at the injection site may occasionally last for at least 14 days.

4.7 Use during pregnancy, lactation or lay

The vaccine 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 from concurrent use of this vaccine with any other. It is therefore recommended that no other vaccine should be administered within 14 days before or after vaccination with this product.

4.9 Amounts to be administered and administration route

Intramuscular injection in sows/gilts of 2 ml of the vaccine per animal in the neck in the area behind the ear.

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.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

No undesirable effects other than those observed and mentioned in the “Adverse reactions” section have been observed.

4.11 Withdrawal period(s)

Zero days.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: inactivated bacterial vaccine. ATC vet code: QI09AB02.

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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Polysorbate 80
Potassium Chloride
Potassium Dihydrogen Phosphate
Simethicone emulsion
Sodium chloride
Disodium Phosphate Dihydate
DL-Alpha-Tocopherol Acetate
Water for injection

6.2 Incompatibilities

Do not mix with any other vaccine or immunological product.

6.3 Shelf life

2 years.
Shelf-life after first opening: 3 hours.

6.4. Special precautions for storage

Store in a refrigerator (+2°C to +8°C). Do not freeze.

6.5 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.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products 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/2/96/001/003-008

9. DATE OF RENEWAL OF THE AUTHORISATION

10 DATE OF REVISION OF THE TEXT

{MM/YYYY} or <month YYYY>

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.