

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:

<i>E. coli</i> : 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

MSD Animal Health UK Ltd.

14. MARKETING AUTHORISATION NUMBERS

Vm 01708/5058

15. BATCH NUMBER

Lot {number}

**PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE
GLASS or PET VIAL LABEL (20, 50 and 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:

<i>E. coli</i> : 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

MSD Animal Health UK Ltd.

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 Diluvac Forte



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.

PARTICULARS TO APPEAR ON THE 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:

- | | |
|---|--|
| - <i>Escherichia coli</i> , fimbrial adhesin F4ab | ≥ 9.0 log ₂ Ab titre ¹ |
| - <i>Escherichia coli</i> , fimbrial adhesin F4ac | ≥ 5.4 log ₂ Ab titre ¹ |
| - <i>Escherichia coli</i> , fimbrial adhesin F5 | ≥ 6.8 log ₂ Ab titre ¹ |
| - <i>Escherichia coli</i> , fimbrial adhesin F6 | ≥ 7.1 log ₂ Ab titre ¹ |
| - <i>Escherichia coli</i> , 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

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 enterotoxigenosis 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
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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 at:

Website: <https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine>

e-mail: adverse.events@vmd.gov.uk

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.

Shelf life after first opening the immediate packaging: 3 hours.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater.

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

Vm 01708/5058

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.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

16. Contact details

Marketing authorisation holder and contact details to report suspected adverse reactions:

MSD Animal Health UK Limited
Walton Manor, Walton
Milton Keynes
MK7 7AJ, United Kingdom
Tel.: +44 (0)1908 685685

Manufacturer responsible for batch release:

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

17. Other information

POM-

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 enterotoxigenic colitis 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.

Gavin Hall
Approved: 22 December 2025