Part II

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Suvaxyn E coli P4

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Ingredient	Per dose (2.0ml)
Escherichia coli K88 antigen	≥25.0 µg
Escherichia coli K99 antigen	≥12.5 µg
Escherichia coli 987P antigen	≥12.5 µg
Escherichia coli F41 antigen	≥15.0 µg
Constituents	
Disodium Phosphate	21.50 mg
Formaldehyde Solution (0.2% w/v)	4.0 mg
Carbopol 941	2.0 mg
Phenol Red	0.1 µg
Deionised water	ad 2.0 ml

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Suspension for injection.

4 CLINICAL PARTICULARS

4.1 Target Species

Swine (sows and gilts).

4.2 Indications for use, specifying the target species

To reduce mortality and clinical signs due to neonatal diarrhoea, caused by enteropathogen strain of *Escherichia coli* which possess the adhesive factors K88, K99, 987P or F41.

4.3 Contraindications

Do not vaccinate sick animals.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

In the event of an allergic or anaphylactic reaction immediate treatment should be given with a soluble glucocorticoid intravenously (e.g. dexamethasone sodium phosphate) or adrenaline intramuscularly.

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

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

4.6 Adverse reactions (frequency and seriousness)

Approximately 8% of vaccinated pigs exhibited fever after vaccination. This fever resolved within 6 hours. Cutaneous swelling, which resolved within 2 days, was seen in approximately 23% of the pigs.

4.7 Use during pregnancy, lactation or lay

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

4.9 Amounts to be administered and administration route

Dose: 1 dose = 2ml.
Administration:
Shake the vial well before use.
Vaccinate only intramuscularly in the neck behind the ear, using the correct vaccination techniques.
Avoid stress in the animals around the time of injection.

Basic Vaccination Schedule:
Sows and gilts, which have not been vaccinated before, must be vaccinated twice with one dose at 4 and 2 weeks before the expected date of farrowing.

Re-Vaccination Scheme:
Booster vaccinations with one dose of vaccine must be given every successive pregnancy between 4 and 2 weeks before the expected date of farrowing.

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

No reactions other than those outlined in Section 4.6 are observed.

4.11 Withdrawal Period(s)

Zero days.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

The vaccine is intended for the passive protection of piglets, receiving colostrum from vaccinated gilts/sows, against neonatal diarrhoea caused by the enteropathogen strain of *Escherichia coli* which possess the adhesive factors K88, K99, 987P or F41.

ATC vet code: QI09AB

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Disodium Phosphate
Phenol Red
De-ionised water

6.2 Incompatibilities

Do not mix with any other vaccine/immunological product.

6.3 Shelf-life

Use immediately on opening.
When stored at 2°C to 8°C, the shelf-life of the vaccine is 30 months.

6.4 Special precautions for storage

Prevent the vaccine from freezing or exposure to heat and/or direct sunlight. The product is to be stored in the dark at a temperature of +2°C to +8°C in an unopened and undamaged vial.

6.5 Nature and composition of immediate packaging

Nature: Polyethylene bottles, sterile, 20 ml (10 doses) and 100ml (50 doses).
Content: Liquid.
Stoppers: Flat, butyl rubber stoppers, sterile.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

Any unused product or waste material should be disposed of in accordance with national requirements.

7 MARKETING AUTHORISATION HOLDER

Fort Dodge Animal Health Limited,
Flanders Road, Hedge End,
Southampton,
SO30 4QH,
UK

8 MARKETING AUTHORISATION NUMBER(S)

VPA No 10861/51/1

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

4th November 2002