Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Porcilis Coli 6C.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

ACTIVE SUBSTANCES	**Per 5 ml dose**
Cell-free pilus antigen of *E.coli* K88ab	100 – 135 Units*
Cell-free pilus antigen of *E.coli* K88ac	100 – 135 Units*
Cell-free pilus antigen of *E.coli* K99	190 – 250 Units*
Cell-free pilus antigen of *E.coli* 987p	2900 – 3100 units*
Purified toxoids of *Cl. Perfringens* Type B and purified toxoids of Types C and D	Together contributing not less than 300 IU** equivalents beta toxoid and not less than 200 IU** equivalents of epsilon toxoid.
ADJUVANT	
Aluminium hydroxide	Less than 15 mg aluminium
PRESERVATIVE	
Thiomersal	0.01% w/v

For a full list of excipients, see section 6.1.
* relative to the potency of the reference batch in accordance with Ph. Eur. 962
** IU = International Unit

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

A combined *E. coli* and *Cl. perfringens* Types B, C and D vaccine for pigs.
For the passive protection of piglets by the active immunisation of breeding sows and gilts, to reduce mortality and clinical signs due to neonatal colibacillosis and enteritis.

4.3 Contraindications

None.

4.4 Special warnings for each target species

Vaccinate only healthy animals.

4.5 Special precautions for use

Special precautions for use in animals
None.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
None.

4.6 Adverse reactions (frequency and seriousness)

Occasional hypersensitivity reactions may accor. Prompt subcutaneous administration of adrenaline may relieve the condition. In most pigs, a slight to moderate swelling (up to 6 cm) may be seen at the injection site after vaccination. The swelling will decline and disappear but may last from 14 to 21 days in some pigs.

4.7 Use during pregnancy, lactation or lay

The vaccine is safe for use during pregnancy. No information is available on specific use during lactation.

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: Sows and gilts 5 ml.
Administration: By subcutaneous injection, preferably behind the ear. The bottle should be well shaken before the vaccine is withdrawn.
Dosage schedule: The initial course consists of two doses:
Basic vaccination scheme: At service, or if necessary, at any time up to six weeks before farrowing.
Re-vaccination scheme: Two weeks before farrowing is expected.
Syringes and needles should be sterilised before use and injection should be made through an area clean, dry skin, taking precaustions against contamination.

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

None other than those listed in section 4.6 above for a single dose.

4.11 Withdrawal Period(s)

Zero days.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

To stimulate passive immunity against *E. coli* diarrhoea and *Cl. perfringens* Type C necrotising infectious enteritis. Passive immunity is confered via the colostrum of vaccinated sows.
ATC Vet code: QI09AB08

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Aluminium Hydroxide
Thiomersal
Sodium chloride

6.2 Incompatibilities

Do not mix with any other medicinal products.

6.3 Shelf-life

18 months.Once broached, use immediately.

6.4 Special precautions for storage

Store and transport refrigerated (2 °C - 8 °C). Protect from light. Do not freeze.

6.5 Nature and composition of immediate packaging

Cardboard box containing 1 x 50 ml (10 dose) flexible LDPE plastic bottles closed with a rubber closure and sealed with an aluminium crimp.

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

Any unused veterinary medicinal product or waste materials derived from the use of such veterinary medicinal products should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Intervet Ireland Ltd,
Magna Drive
Magna Business Park
Citywest Road
Dublin 24

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10996/247/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

4th November 2011

10 DATE OF REVISION OF THE TEXT