1 NAME OF THE VETERINARY MEDICINAL PRODUCT

GLETVAX 6

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

ACTIVE SUBSTANCES	**Per 5 ml dose**
Cell-free pilus antigen of *E.coli*K88ab	≥14.6 log_2antibody titre*
Cell-free pilus antigen of *E.coli*K88ac	≥15.5 log_2antibody titre *
Cell-free pilus antigen of *E.coli*K99	≥12.2 log_2antibody titre *
Cell-free pilus antigen of *E.coli*987p	≥13.1 log_2antibody titre *
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	Less than 0.575 mg

For a full list of excipients, see section 6.1.

* Antibody titre obtained in the potency test in mice 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 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 occur. 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 of this vaccine when used with any other veterinary medicinal 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.

4.9 Amounts to be administered and administration route

Dose: Sows and gilts 5 ml.

Administration:
By subcutaneous or intramuscular 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 injectionshould be made through an area of clean, dry skin,
taking precautions 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 conferred 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 other medicinal product.

6.3 Shelf-life

Shelf life of the veterinary medicinal product as packaged for sale: 24 months.

Use immediately after broaching.

6.4 Special precautions for storage

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

6.5 Nature and composition of immediate packaging

Cardboard box containing 1 x 10 dose HDPE plastic bottle closed with a chlorobutyl rubber closure and sealed with an aluminium crimp.

Cardboard box containing 1 x 20 dose HDPE plastic bottle closed with a chlorobutyl rubber closure and sealed with an aluminium crimp.

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 the use of such veterinary medicinal products should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Zoetis Belgium S.A.
2nd Floor, Building 10
Cherrywood Business Park
Loughlinstown
Co Dublin
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA10387/035/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 12th September 2002

Date of last renewal: 11th September 2007

10 DATE OF REVISION OF THE TEXT

September 2017