

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Gletvax 6 suspension for injection

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 ml dose contains:

### Active substances:

Cell-free pilus antigen of <i>E.coli</i> K88ab	≥14.6 log <sub>2</sub> antibody titre*
Cell-free pilus antigen of <i>E.coli</i> K88ac	≥15.5 log <sub>2</sub> antibody titre *
Cell-free pilus antigen of <i>E.coli</i> K99	≥12.2 log <sub>2</sub> antibody titre *
Cell-free pilus antigen of <i>E.coli</i> 987p	≥13.1 log <sub>2</sub> antibody titre *
Purified toxoids of <i>Cl. Perfringens</i> 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.

\* Antibody titre obtained in the potency test in mice in accordance with Ph. Eur. 962

\*\* IU = International Unit

### Adjuvant

Aluminium hydroxide Less than 15 mg aluminium

### Excipients:

Qualitative composition of excipients and other constituents	Quantitative composition if that information is essential for proper administration of the veterinary medicinal product
Thiomersal	Less than 0.575 mg
Sodium Chloride	

Aqueous opalescent suspension which, on standing, separates into a whitish lower layer and a clear upper layer.

## 3. CLINICAL INFORMATION

### 3.1 Target species

Pigs (sows and gilts).

### 3.2 Indications for use for each 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.

### 3.3 Contraindications

None.

### 3.4 Special warnings

Vaccinate healthy animals only.

### 3.5 Special precautions for use

Special precautions for safe use in the target species:

Not applicable.

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

Not applicable.

Special precautions for the protection of the environment:

Not applicable.

### 3.6 Adverse events

Pigs (sows and gilts).

Very common (>1 animal / 10 animals treated):	Injection site swelling <sup>1</sup>
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Hypersensitivity reaction <sup>2</sup>

<sup>1</sup> Up to 6 cm. The swelling will decline and disappear but may last from 14 to 21 days in some pigs.

<sup>2</sup> Prompt subcutaneous administration of adrenaline may relieve the condition.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

### 3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:

Can be used during pregnancy.

The safety of the veterinary medicinal product has not been established during lactation.

### 3.8 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.

### 3.9 Administration routes and dosage

Subcutaneous or intramuscular use.

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 injection should be made through an area of clean, dry skin, taking precautions against contamination.

### **3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)**

None other than those listed in section 3.6 above for a single dose.

### **3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance.**

Not applicable.

### **3.12 Withdrawal periods**

Zero days.

## **4. IMMUNOLOGICAL INFORMATION**

### **4.1 ATCvet code: QI09AB08**

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.

## **5. PHARMACEUTICAL PARTICULARS**

### **5.1 Major incompatibilities**

Do not mix with any other veterinary medicinal product.

### **5.2 Shelf life**

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

Shelf life after first opening the immediate packaging: Use immediately.

### **5.3 Special precautions for storage**

Store and transport refrigerated (2 °C – 8 °C).

Do not freeze.

Protect from light.

### **5.4 Nature and composition of immediate packaging**

HDPE plastic bottle closed with a chlorobutyl rubber closure and sealed with an aluminium crimp.

Pack sizes:

Cardboard box containing 1 x 10 dose.

Cardboard box containing 1 x 20 dose.

Not all pack sizes may be marketed.

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

Medicines should not be disposed of via wastewater or household waste.

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 national collection systems applicable to the veterinary medicinal product concerned.

**6. NAME OF THE MARKETING AUTHORISATION HOLDER**

Zoetis Belgium S.A.

**7. MARKETING AUTHORISATION NUMBER**

VPA10387/035/001

**8. DATE OF FIRST AUTHORISATION**

29/08/2013

**9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS**

11/12/2024

**10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS**

Veterinary medicinal product not subject to prescription.

Detailed information on this veterinary medicinal product is available in the [Union Product Database \(https://medicines.health.europa.eu/veterinary\)](https://medicines.health.europa.eu/veterinary).