SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Gletvax 6

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

	per 5 ml dose
Active Substances	
E. coli K88ab (F4ab)	At least 14.6 $\log_2$ antibody titre[1]
E. coli K88ac (F4ac)	At least 15.5 $\log_2$ antibody titre[1]
E. coli K99 (F5)	At least 12.2 $\log_2$ antibody titre[1]
E. coli 987P (F6)	At least 13.1 $\log_2$ antibody titre[1]
Purified toxoids of *Cl. perfringens* Type B and purified toxoids of Types C and D	Together contributing not less than 300 international unit equivalents beta toxoid and not less than 200 International Unit equivalents of epsilon toxoid
Adjuvant	
Aluminium Hydroxide	Less than 15mg aluminium
Excipients	
Thiomersal	0.01% w/v

[1]Antibody titre obtained in the potency test in mice

For a full list of excipients, see section 6.1

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 prevent neonatal colibacillosis caused by K99 bearing strains of *E. coli;* reduce neonatal colibacillosis caused by K88ab, K88ac and 987P bearing strains of *E.coli* and *Cl. perfringens* Type C necrotising infectious enteritis.

4.3 Contra-indications

None.

4.4 Special warnings for each target species

Vaccinate only healthy animals.

4.5 Special precautions for use, including special precautions to be taken by the person administering the medicinal products to animals

i. Special precautions for use in animals

Syringes and needles should be sterilised before use and injection should be made through an area of clean, dry skin, taking precautions against contamination.

ii. 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.

4.6 Adverse reactions (frequency and seriousness)

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.

Hypersensitivity reactions may occur very rarely. Prompt subcutaneous administration of adrenaline may relieve the condition.

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 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 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.

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

After routine vaccination, 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. No increased reactions have been seen after administration of an overdose.

4.11 Withdrawal period

Zero days.

5. IMMUNOLOGICAL PROPERTIES

To stimulate active immunity in order to provide passive immunity to the progeny against neonatal colibacillosis caused by K99, K88ab, K88ac and 987P bearing strains of *E. coli* and necrotising infectious enteritis due to *C. perfringens* Type C.

ATCVet 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

24 months.
Use immediately after broaching.

6.4 Special precautions for storage

Store and transport between +2 °C and +8 °C. Protect from light. Do not freeze.

6.5 Nature and composition of immediate packaging

50 ml (10 dose) and 100ml (20 dose) flexible HDPE plastic bottles closed with a 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 AUTORISATION HOLDER

Zoetis Belgium S.A.
2nd Floor, Building 10
Cherrywood Business Park
Loughlinstown
Dublin 18
D18 T3Y1
Ireland

8. MARKETING AUTHORISATION NUMBER

Vm 60021/3077

9. DATE OF FIRST AUTHORISATION

28 October 2005

10. DATE OF REVISION OF THE TEXT

May 2025

Gavin Hall
Approved: 22 May 2025