

**ANNEX III**  
**LABELLING AND PACKAGE LEAFLET**

## **A. LABELLING**

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

**Gletvax 6 – Carton**  
**10 dose (50 ml)**  
**20 dose (100 ml)**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Gletvax 6

**2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES**

Combined Porcine *E. coli* and *Cl. perfringens* Types B, C and D Vaccine.

Each 5 ml dose contains

*E.coli* K88ab (F4ab)  $\geq 14.6 \log_2$  antibody titre

*E.coli* K88ac (F4ac)  $\geq 15.5 \log_2$  antibody titre

*E.coli* K99 (F5)  $\geq 12.2 \log_2$  antibody titre

*E.coli* 987P (F6)  $\geq 13.1 \log_2$  antibody titre

Purified toxoids of *Cl. Perfringens* Type B and purified toxoids of Types C and D together contributing not less than 300 international beta toxoid and not less than 200 International Unit equivalents of epsilon toxoid.

Antigens are absorbed on to aluminium hydroxide gel as the adjuvant.

Preservative: Thiomersal 0.01% w/v.

**3. PHARMACEUTICAL FORM**

Suspension for Injection

**4. PACKAGE SIZE**

50 ml

100 ml

**5. TARGET SPECIES**

Sows and gilts

**6. INDICATION(S)**

**7. METHOD AND ROUTE(S) OF ADMINISTRATION**

Dose: Sows and gilts 5 ml.  
For subcutaneous injection.  
For full information, see package leaflet.

**8. WITHDRAWAL PERIOD**

**Withdrawal period:** zero days.

**9. SPECIAL WARNING(S), IF NECESSARY**

**Important:** read instructions before use.

**10. EXPIRY DATE**

Use by:  
Use immediately after broaching.

**11. SPECIAL STORAGE CONDITIONS**

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

**12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY**

**Important:** read instructions before use.

**13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE**

For animal treatment only.

**POM-VPS**

To be supplied only on veterinary prescription.

**14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”**

Keep out of reach and sight of children.

**15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER**

**MA Holder:**

Zoetis UK Limited  
1st Floor, Birchwood Building  
Springfield Drive  
Leatherhead  
Surrey  
KT22 7LP

**16. MARKETING AUTHORISATION NUMBER**

Vm 42058/4070

**17. MANUFACTURER'S BATCH NUMBER**

Lot:

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS**

**Gletvax 6 – vial label**  
**10 dose (50 ml)**  
**20 dose (100 ml)**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Gletvax 6  
Suspension for Injection

**2. QUANTITY OF THE ACTIVE SUBSTANCE(S)**

**Each 5 ml dose contains:**

*E.coli* K88ab (F4ab)  $\geq 14.6 \log_2$  antibody titre  
*E.coli* K88ac (F4ac)  $\geq 15.5 \log_2$  antibody titre  
*E.coli* K99 (F5)  $\geq 12.2 \log_2$  antibody titre  
*E.coli* 987P (F6)  $\geq 13.1 \log_2$  antibody titre

Purified toxoids of *Cl. Perfringens* Type B and purified toxoids of Types C and D together contributing not less than 300 international beta toxoid and not less than 200 International Unit equivalents of epsilon toxoid.

Preservative: Thiomersal 0.01% w/v.

**3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES**

50 ml  
100 ml

**4. ROUTE(S) OF ADMINISTRATION**

**Dose:**

Sows and gilts 5 ml.  
For subcutaneous injection.

**5. WITHDRAWAL PERIOD**

**Withdrawal period:** Zero days.

**6. BATCH NUMBER**

Lot:

**7. EXPIRY DATE**

Use by:

**8. THE WORDS "FOR ANIMAL TREATMENT ONLY"**

For animal treatment only.  
Keep the container in the outer carton.  
For full information, see package leaflet.

Vm 42058/4070

POM-VPS

**MA Holder:**

Zoetis UK Limited  
1st Floor, Birchwood Building  
Springfield Drive  
Leatherhead  
Surrey  
KT22 7LP

## **B. PACKAGE LEAFLET**



**PACKAGE LEAFLET FOR:**  
Gletvax 6 Suspension for Injection  
Combined Porcine *E. coli* and *Cl. perfringens* Types B, C and D Vaccine.

**1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT**

Marketing authorisation holder:

Zoetis UK Limited  
1st Floor, Birchwood Building  
Springfield Drive  
Leatherhead  
Surrey  
KT22 7LP

Manufacturer responsible for batch release:

Zoetis Belgium SA  
Rue Laid Burniat 1  
1348 Louvain-la-Neuve  
Belgium

**2. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Gletvax 6

**3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)**

Each 5 ml dose contains:

<i>E. coli</i> K88ab (F4ab)	≥ 14.6 log <sub>2</sub> antibody titre <sup>1</sup>
<i>E. coli</i> K88ac (F4ac)	≥ 15.5 log <sub>2</sub> antibody titre <sup>1</sup>
<i>E. coli</i> K99 (F5)	≥ 12.2 log <sub>2</sub> antibody titre <sup>1</sup>
<i>E. coli</i> 987P (F6)	≥ 13.1 log <sub>2</sub> antibody titre <sup>1</sup>
Purified toxoids of <i>Cl. Perfringens</i> Type B purified toxoids of Types C and D	At least 300 i.u. and equivalents of beta toxoid and not less than 200 i.u. equivalents of epsilon toxoid.

<sup>1</sup> Antibody titre obtained in the potency test in mice

**Presentation:**

A fluid vaccine with a precipitate which resuspends on shaking.  
The vaccine contains cell-free pilus antigens of *E. coli*, strains K88ab, K88ac, K99 and 987P bacterin toxoid of *Cl. perfringens* Type B and purified toxoids of Types C and D all absorbed on to aluminium hydroxide gel as the adjuvant. Thiomersal (0.01% w/v) is added as preservative.

**4. INDICATION(S)**

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.

## 5. CONTRAINDICATIONS

None

## 6. ADVERSE REACTIONS

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.

## 7. TARGET SPECIES

Sows and gilts

## 8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

**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.

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.

## 9. ADVICE ON CORRECT ADMINISTRATION

Shake well before use.

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

## 10. WITHDRAWAL PERIOD

**Withdrawal period:** Zero days.

## 11. SPECIAL STORAGE PRECAUTIONS

Keep out of reach and sight of children.

Store between +2°C +8°C.

Protect from light.

Do not freeze.

Use immediately after broaching.

## 12. SPECIAL WARNING(S)

Vaccinate only healthy animals.

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

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.

Do not mix with any other medicinal products.

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

## 13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

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

## 14. PID LINK (Do not print heading)

*[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]*

Find more product information by searching for the 'Product Information Database' on [www.gov.uk](http://www.gov.uk).

## 15. OTHER INFORMATION

**Important:** read before use.

For animal treatment only.

Legal Category: POM-VPS

Prescription-only Medicine – Veterinarian, Pharmacist or Suitably Qualified Person.

To be supplied only on veterinary prescription.

Package quantity:           1 x 50 ml (10 doses) vial  
  1 x 100 ml (20 doses) vial

Not all pack sizes may be marketed.

### Further information:

In any animal population there may be a small number of individuals which may fail to respond to vaccination. Successful vaccination depends upon correct storage and administration of the vaccine together with the animal's ability to respond. This can be influenced by such factors as genetic constitution, intercurrent infection, age, the presence of maternally- derived antibodies, nutritional status, concurrent drug therapy and stress.

**Marketing Authorisation number:** Vm 42058/4070

*Gavin Hall*  
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