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) ≥ 14.6 $\log_2$ antibody titre
E.coli K88ac (F4ac) ≥ 15.5 $\log_2$ antibody titre
E.coli K99 (F5) ≥ 12.2 $\log_2$ antibody titre
E.coli 987P (F6) ≥ 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) ≥ 14.6 $\log_2$ antibody titre
E.coli K88ac (F4ac) ≥ 15.5 $\log_2$ antibody titre
E.coli K99 (F5) ≥ 12.2 $\log_2$ antibody titre
E.coli 987P (F6) ≥ 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:

E.coli K88ab (F4ab)	≥ 14.6 $\log_2$ antibody titre[1]
E.coli K88ac (F4ac)	≥ 15.5 $\log_2$ antibody titre[1]
E.coli K99 (F5)	≥ 12.2 $\log_2$ antibody titre[1]
E.coli 987P (F6)	≥ 13.1 $\log_2$ antibody titre[1]
Purified toxoids of *Cl. Perfringens* Type B	At least 300 i.u. and equivalents of beta toxoid and not less than 200 i.u. equivalents of epsilon toxoid.
purified toxoids of Types C and D	

[1] 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.

Occasional hypersensitivity reactions may occur. 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.

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. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

August 2020

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 a genetic constitution, intercurrent infection, age, the presence of maternally- derived antibodies, nutritional status, concurrent drug therapy and stress.

Marketing Authorisation number: Vm 42058/4070

Approved 19 August 2020