PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Outer carton 50 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Lambivac

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Inactivated vaccine containing per ml: *Clostridium perfringens* beta toxoid, inducing ≥ 10 IU; *Clostridium perfringens* epsilon toxoid, inducing ≥ 5 IU; *Clostridium tetani* toxoid, inducing ≥ 2.5 IU.

Also contains Aluminium hydroxide as an adjuvant and 0.13 mg/ml Thiomersal as preservative

3. PHARMACEUTICAL FORM

Suspension for injection.

4. PACKAGE SIZE

50 ml (25 x 2ml doses)

100 ml (50 x 2ml doses)

5. TARGET SPECIES

Sheep and pigs.

6. INDICATION(S)

Suspension for injection for pigs and sheep against lamb dysentery, struck, pulpy kidney and tetanus.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

NON-COLLAPSIBLE BOTTLE

Vaccinator with vented draw-off spike or similar device must be used.

Shake well before use.

Dosage: Sheep 2ml, Pigs 5ml, for subcutaneous injection.

8. WITHDRAWAL PERIOD

Withdrawal period(s) Zero days.

9. SPECIAL WARNING(S), IF NECESSARY

Read package leaflet before use.

10. EXPIRY DATE

Expiry end of:

In-use shelf life: 10 hours

11. SPECIAL STORAGE CONDITIONS

Store in a refrigerator at +2ºC to +8ºC.

Do not freeze.

Keep container in the outer carton.

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

Read package the leaflet before use.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

[Distribution category]

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:
MSD Animal Health UK Ltd.
Walton Manor
Walton
Milton Keynes
MK7 7AJ

Distributed in Northern Ireland by:
Intervet Ireland Ltd.
Magna Drive
Magna Business Park
Citywest Road,
Dublin 24

16. MARKETING AUTHORISATION NUMBER

Vm 01708/4509

17. MANUFACTURER'S BATCH NUMBER

Batch

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING

100 ml Label

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Lambivac

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Vaccine containing per ml: *C. perfringens* β toxoid, inducing ≥ 10 IU; *C. perfringens* ε toxoid, inducing ≥ 5 IU; *C. tetani* toxoid, inducing ≥ 2.5 IU.

Also contains Aluminium hydroxide and 0.13 mg/ml Thiomersal as preservative

3. PHARMACEUTICAL FORM

Suspension for injection for pigs and sheep.

4. PACKAGE SIZE

100 ml (50 x 2ml doses)

5. TARGET SPECIES

Sheep and pigs.

6. INDICATION(S)

Not applicable

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Shake well before use.

Dosage: Sheep 2ml, Pigs 5ml, for subcutaneous injection

Read package leaflet before use.

8. WITHDRAWAL PERIOD

Withdrawal period(s) Zero days.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

Expiry end of:

In-use shelf life: 10 hours

11. SPECIAL STORAGE CONDITIONS

Store in a refrigerator at +2ºC to +8ºC.

Do not freeze.

Keep container in the outer carton.

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

Read package leaflet before use.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

[Distribution category]

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:
MSD Animal Health UK Ltd.
Walton Manor
Walton
Milton Keynes
MK7 7AJ

16. MARKETING AUTHORISATION NUMBER

Vm 01708/4509

17. MANUFACTURER'S BATCH NUMBER

Batch

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

50 ml Vial Label

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Lambivac

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Vaccine containing per ml: *C. perfringens* β toxoid, inducing ≥ 10 IU; *C. perfringens* ε toxoid, inducing ≥ 5 IU; *C. tetani* toxoid, inducing ≥ 2.5 IU.

Also contains Aluminium hydroxide and Thiomersal.

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

50 ml (25 x 2ml doses)

4. ROUTE(S) OF ADMINISTRATION

Suspension for injection for pigs and sheep.

5. WITHDRAWAL PERIOD

Withdrawal period: Zero days

6. BATCH NUMBER

Batch

7. EXPIRY DATE

Expiry end of:

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

Keep container in the outer carton.

Vm 01708/4509

POM-VPS

PACKAGE LEAFLET FOR:

Directions for Use

Lambivac

Suspension for injection in sheep and pigs

When starting the Lambivac vaccination programme, two doses of vaccine must be given…

…thereafter, a single booster dose is required.

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

MA holder

MSD Animal Health UK Ltd.
Walton Manor
Walton
Milton Keynes
Buckinghamshire
MK7 7AJ

Manufacturer[1]
Intervet International B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
The Netherlands

MSD Animal Health UK Limited
Walton Manor
Walton
Milton Keynes
Bucks, MK7 7AJ

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Lambivac

Suspension for injection in sheep and pigs

[1] The printed package leaflet will state the name and address of the manufacturer responsible for the release of the concerned batch only.

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

Presentation

Suspension for injection containing per ml *Clostridium perfringens* beta toxoid, inducing ≥ 10 IU; *Clostridium perfringens* epsilon toxoid, inducing ≥ 5 IU; *Clostridium tetani* toxoid, inducing ≥ 2.5 IU. Also contains Aluminium hydroxide as an adjuvant and 0.13 mg/ml Thiomersal as preservative

4. INDICATION(S)

Uses

Sheep

For the active immunisation of sheep to:

– reduce clinical signs and mortality due to the toxin of *Clostridium tetani* (Tetanus);

– reduce mortality due to the epsilon toxin of *Clostridium perfringens* (Pulpy kidney);

– induce a serological response against the beta toxin of *Clostridium perfringens* (Struck, Lamb dysentery).

The vaccine may be used in pregnant ewes to provide passive immunisation of lambs, provided that the lambs receive sufficient immune colostrum during the first 12 hours of life, to:

– reduce clinical signs and mortality due to the toxin of *Costridium tetani* (Tetanus);

– reduce mortality due to the epsilon toxin of *Clostridium perfringens* (Pulpy kidney)

– induce a serological response against the beta toxin of *Clostridium perfringens* (Lamb dysentery).

Significant levels of immunity cannot be expected until two weeks after the second dose of vaccine in the primary vaccination course.

From experience from field use, the duration of active immunity in lambs and sheep is expected to last one year. The duration of passive protection in lambs is approximately 12 weeks provided that the lambs receive sufficient immune colostrum during the first 12 hours of life.

Pigs

For active immunisation of sows against tetanus caused by *Clostridium tetani*.

Significant levels of immunity cannot be expected until two weeks after the second dose of vaccine in the primary vaccination course. From experience from field use, the duration of active immunity in pigs is expected to last one year.

The vaccine may be used in pregnant sows to provide passive immunisation of piglets, provided that the piglets receive sufficient immune colostrum during the first 12 hours of life, to:

– reduce clinical signs and mortality due to the toxin of *Clostridium tetani* (Tetanus);

– induce a serological response against the toxin of *Clostridium perfringens* type C (enterotoxemia).

The duration of the passive protection in piglets is 14 days.

5. CONTRAINDICATIONS

Contra-indications, warnings, etc.

Occasional hypersensitivity may occur.

Vaccination may result in small (<10 cm) transient injection site reactions possibly lasting for up to 3-4 months after vaccination.

Local tissue irritating effects of alhydrogel-adjuvanted vaccines reveal granulomatous inflammatory reactions consisting mainly of activated macrophages containing foamy cytoplasm, epithelioid cells, small lymphocytes and multinuclear giant cells.Reactions similar to those described above were observed following administration of a double dose.

In any group of animals, a small number of individuals may fail to respond to vaccination as a result of immunological incompetence. Satisfactory immune responses will only be attained in healthy animals, thus it is important to avoid vaccination of animals which have an intercurrent infection or metabolic disorder.

When handling animals, stress should be avoided, particularly during the later stages of pregnancy when there is a risk of inducing abortion and metabolic disorders.

The nutritional and metabolic status of pregnant ewes is extremely important at the time of vaccination. If in doubt, advice should be sought from a veterinary surgeon.

No information is available on the efficacy of the vaccine in young animals with maternally derived antibodies.

No information is available on the safety and efficacy of this vaccine with any other veterinary medicinal product. A decision to use this vaccine before or after any other veterinary medicinal product is therefore on a case by case basis. Do not mix with any other veterinary medicinal product.

Operator warnings

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

Withdrawal period(s)

Zero days.

6. ADVERSE REACTIONS

See "Contra-indications, warnings, etc." section above

7. TARGET SPECIES

Sheep and pigs.

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

Dosage and administration

The vaccine should be administered by subcutaneous injection in the lateral side of the upper neck observing aseptic precautions.

Ewes and sows can be vaccinated during late pregnancy.

Sheep and lambs: 2 ml/dose

Pigs: 5 ml/dose

Sheep

All sheep from 3 weeks of age onwards and not previously vaccinated with Lambivac must receive two injections separated by an interval of 4-6 weeks to be completed before onset of the period of risk. Thereafter they should receive booster injections 2-3 weeks prior to identified risk periods with intervals of not more than 12 months. In adult breeding ewes these yearly booster injections should be given during the pre-lambing period, 4-6 weeks pre-lambing, to allow passive protection of lambs via colostrum.

Pigs

Two injections with an interval of at least 3 weeks between injections, the second dose to be administered at least 3 weeks before farrowing. The preferred schedule is vaccination at 6 and 3 weeks prior to the expected date of farrowing. Only a single booster dose is required in subsequent pregnancies at approximately 3-4 weeks pre-farrowing.

The vaccine bottle must be shaken well before use.

Syringes and needles must be from gamma irradiated packs or freshly sterilised by boiling for at least 20 minutes. No alcohol or other disinfectants should be used for sterilisation.

The use of an automatic vaccinator is recommended. Since the bottle is non-collapsible, a vaccinator with a vented draw-off spike or similar device must be used. The instructions supplied with such equipment should be noted and care should be taken to ensure the delivery of the full dose, particularly with the final few doses from the bottle.

9. ADVICE ON CORRECT ADMINISTRATION

See "Dosage and administration" section above

10. WITHDRAWAL PERIOD(S)

See "Contra-indications, warnings, etc." section above

11. SPECIAL STORAGE PRECAUTIONS

Pharmaceutical precautions

Store in a refrigerator (2ºC - 8ºC).

Do not freeze.

Keep the container in the outer carton.

Shelf-life after first opening the container: 10 hours

12. SPECIAL WARNING(S)

See "Contra-indications, warnings, etc." section above

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

Disposal advice

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

Date of text preparation

October 2020

15. OTHER INFORMATION

FOR ANIMAL TREATMENT ONLY.

KEEP OUT OF THE REACH AND SIGHT OF CHILDREN.

Legal category

POM-VPS

To be supplied only on veterinary prescription

Package quantities

Cartons containing of 50 ml or 100ml polyethylene multidose bottle, closed with a combination seal. Not all presentations may be marketed.

MA number

Vm 01708/4509

Distributed in Northern Ireland by
Intervet Ireland Ltd.
Magna Drive
Magna Business Park
Citywest Road
DUBLIN 24