SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Lambivac

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance(s):	**per ml**
Clostridium perfringens beta toxoid inducing	≥ 10 IU
Clostridium perfringens epsilon toxoid inducing	≥ 5 IU
Clostridium tetani toxoid inducing	≥ 2.5 IU
Adjuvant(s):	
Aluminium hydroxide gel	250 mg
Excipients*:*	
Thiomersal (preservative)	0.13 mg
Formaldehyde	<0.2 mg

For a full list of excipients see section 6.1.

3. PHARMACEUTICAL FORM

Suspension for injection.

4. CLINICAL PARTICULARS

4.1 Target species

Sheep and pigs.

4.2 Indications for use specifying the target species

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 to the toxin of *Clostridium perfringens type C* (Enterotoxemia).

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

4.3 Contraindications

None.

4.4 Special warnings for each target species

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.

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

i. Special precautions for use in animals

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.

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)

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.

4.7 Use during pregnancy, lactation or lay

Ewes and sows can be vaccinated during late pregnancy.

4.8 Interaction with other medicinal products and other forms of interaction

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.

4.9 Amounts to be administered and administration route

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

Sheep and lambs: 2 ml/dose
Pigs: 5 ml/dose

<u>Sheep</u>
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.

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

Reactions similar to those described in section 4.6 were observed following administration of a double dose.

4.11 Withdrawal period(s)

Zero days.

5. IMMUNOLOGICAL PROPERTIES

ATCvet code: Sheep: QI04AB01 Pigs: QI09AB12

To stimulate active immunity and to provide passive immunity to the progeny against clostridial diseases.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Maleic acid
Tris
Sodium chloride
Formaldehyde
Thiomersal
Water for injections

6.2 Incompatibilities

Do not mix with any other veterinary medicinal product.

6.3 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 3 years
Shelf-life after first opening the container: 10 hours

6.4 Special precautions for storage

Store in a refrigerator (2°C - 8°C).
Do not freeze.

6.5 Nature and composition of immediate packaging

Cardboard box with containers of low density polyethylene of 50 and 100 ml volume closed with a rubber disc/stopper and an aluminium cap.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products, if appropriate.

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

7. MARKETING AUTHORISATION HOLDER

Intervet International B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
Netherlands

8. MARKETING AUTHORISATION NUMBER

Vm 06376/4111

9. DATE OF FIRST AUTHORISATION

17 October 2005

10. DATE OF REVISION OF THE TEXT

December 2024

Gavin Hall
Approved: 19 December 2024