SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ovivac P Plus suspension for injection for sheep

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml of vaccine contains:

Active substances:

Clostridium perfringens type D, strain 603 ε toxoid	≥ 5 IU
Clostridium septicum, strain S1110/85 toxoid	≥ 2.5 IU
Clostridium tetani, strain 51123/91 toxoid	≥ 2.5 IU
Clostridium chauvoei, strains 655, 656, 657, 658, 1048 cells and equivalent toxoid	≥ 0.5 guinea pig PD_{90} * per strain
Mannheimia haemolytica, strains A1, A2, A6, A7, A9	5 x 10^8 cells per strain
Pasteurella trehalosi, strains T3, T4, T10, T15	5 x 10^8 cells per strain

* PD_{90} = protective dose 90% survival.

Adjuvant:

Aluminium hydroxide gel	350 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Thiomersal	0.067 - 0.15 mg
Tris	
Maleic acid	
Sodium chloride	
Formaldehyde	
Purified water	

Opaque suspension.

3. CLINICAL INFORMATION

3.1 Target species

Sheep.

3.2 Indications for use for each target species

For the active immunisation of lambs as an aid in the control of pulpy kidney, tetanus, braxy and blackleg caused by *Cl. perfringens* type D, *Cl. septicum*, *Cl. tetani* and *Cl. chauvoei*.
The vaccine may be used as an aid in the control of pneumonic pasteurellosis in sheep of all ages from a minimum age of 3 weeks and in the control of systemic pasteurellosis in weaned fattening and breeding sheep.

Onset of immunity: As with most killed vaccines, significant levels of immunity cannot be expected until two weeks after the second dose of vaccine in the primary vaccination course.

Duration of immunity: Evidence of efficacy of the Pasteurella/Mannheimia component was generated in an experimental infection model using Heptavac P Plus and it is not possible to provide duration of immunity information using this system. There are reports that active immunity will last for up to one year and that passive immunity will persist for up to 4 weeks after birth in lambs from ewes vaccinated with conventional Pasteurella vaccines.

3.3 Contraindications

None.

3.4 Special warnings

Vaccinate healthy animals only.

3.5 Special precautions for use

Special precautions for safe use in the target species:
The veterinary medicinal product should not be used in lambs less than 3 weeks of age.
Should this vaccine be used in breeding stock, 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.
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 intercurrent infection or metabolic disorder.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
In the case of accidental self-injection seek medical advice immediately and show the package leaflet or the label to the physician.

Special precautions for the protection of the environment:
Not applicable.

3.6 Adverse events

Sheep:

Common (1 to 10 animals / 100 animals treated):	Injection site reaction[1]
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Hypersensitivity reaction

[1] The vaccine contains an adjuvant and, as with most adjuvanted vaccines, may result in small transient injection site reactions possibly lasting for up to 3 - 4 months after vaccination.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy:
Ewes may be vaccinated during pregnancy as an aid in the control of pulpy kidney, tetanus and pasteurellosis in their lambs provided that the lambs receive sufficient immune colostrum during the first 1 - 2 days of life. However, this vaccine is not recommended as a breeding stock vaccine due to the lack of a lamb dysentery component. The combined 7 in 1 clostridial plus pasteurella vaccine, Heptavac P Plus, is the recommended breeding stock vaccine since it provides optimal aid in the control of the predominant clostridial diseases in adult sheep by active immunisation and in young lambs by passive immunisation.

Should the veterinary medicinal product be used as a breeding stock vaccine, when handling sheep, stress should be avoided, particularly during the later stages of pregnancy when there is a risk of inducing metabolic disorders which may lead to abortion.

3.8 Interaction with other medicinal products and other forms of interaction

No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal 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.

3.9 Administration routes and dosage

Dose: 2 ml.
Administration: Subcutaneous use.
The vaccine should be administered by subcutaneous injection in the lateral side of the upper neck observing aseptic precautions.

All lambs not previously vaccinated with the veterinary medicinal product must receive two injections, each of 2 ml, separated by an interval of 4 - 6 weeks. Thereafter they must receive booster injections at intervals of not more than 12 months.

On farms where the incidence of pasteurellosis is high, a supplementary booster vaccination with Ovipast Plus (Pasteurella vaccine) may be required 2 - 3 weeks prior to expected seasonal outbreaks.

The veterinary medicinal product should not be used in lambs less than 3 weeks of age due to the possible immunological incompetence of the very young lamb and competition from any maternally derived colostral antibodies. Lambs born to Heptavac P Plus vaccinated ewes will, provided they receive sufficient immune colostrum during the first 1 - 2 days of life, have adequate initial levels of antibody to aid in the control of lamb dysentery, pulpy kidney, tetanus and pasteurellosis. To maintain aid in the control of pulpy kidney, tetanus and pasteurellosis, lambs being retained for late fattening or storing will require a full vaccination course of Ovivac P Plus. At a minimum age of 3 weeks these lambs should receive two injections, each of 2 ml, separated by an interval of 4 - 6 weeks.

Lambs being retained for subsequent breeding will require a full course of vaccination with a suitable breeding stock vaccine. The combined 7 in 1 Clostridial plus Pasteurella vaccine, Heptavac P Plus, is the recommended breeding stock vaccine since it provides optimal aid in the control of the predominant clostridial diseases in adult sheep by active immunisation and in young lambs by passive immunisation.

The vaccine bottle must be shaken well before use.

The vaccine may be administered using a sterile needle and syringe, providing a fresh sterile needle is used each time the rubber cap is punctured, to avoid contamination of the remaining contents.

Syringes and needles must be from gamma irradiated packs or freshly sterilised by boiling for 20 minutes.

It is recommended that an automatic vaccinator is used. Since the bottle containing this product is non-collapsible the vaccinator must have a vented draw-off spike or similar device. The instructions supplied with such syringes 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.

Partially used containers must be discarded at the end of each day's operations.

This vaccine has been developed following research and development which resulted in the application of the 'IRP' technology for the manufacture of the pasteurella components of the vaccine. The inclusion of these IRP components should provide enhanced efficacy and cross protection e.g. protection against serotype A12, which is not included in the vaccine, has been demonstrated. Studies on the response of sheep to these vaccines show that two injections separated by an interval of 4-6 weeks are required to gain the full benefit of the 'IRP'.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

Accidental overdosage is unlikely to cause any reaction other than described in section 3.6. No adverse local or systemic reactions were noted in overdose studies performed in lambs.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Zero days.

4. IMMUNOLOGICAL INFORMATION

4.1 ATCvet code: QI04AB05.

For the immunisation of sheep as an aid in the control of clostridial diseases and pasteurellosis.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product.

5.2 Shelf life

Shelf life of veterinary medicinal product as packaged for sale: 3 years.
Shelf life after first opening the immediate packaging: 10 hours.

5.3 Special precautions for storage

Store in a refrigerator (2 °C – 8 °C).

Do not freeze.
Protect from light.

5.4 Nature and composition of immediate packaging

Low density polyethylene bottle containing 100 ml or 500 ml closed with a combination seal.

Pack sizes:
Cardboard box containing 1 bottle of 100 ml or 500 ml.
Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Intervet International B.V.

7. MARKETING AUTHORISATION NUMBER

Vm 06376/4119

8. DATE OF FIRST AUTHORISATION

27 November 1996

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

August 2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

Gavin Hall

Approved: 22 September 2025