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 epsilon toxoid	inducing	$\geq$ 5 IU
Clostridium septicum S1110/85 toxoid	inducing	$\geq$ 2.5 IU
Clostridium tetani, strain 51123/91 toxoid	inducing	$\geq$ 2.5 IU
Clostridium chauvoei cells and equivalent toxoid of strains 655,656,657,658,1048	inducing	$\geq$ 0.5 guinea pig PD_{90}
Formalin killed cells of *Mannheimia haemolytica* serotypes		
A1	5×10^8	cells
A2	5×10^8	cells
A6	5×10^8	cells
A7	5×10^8	cells
A9	5×10^8	cells
Formalin killed cells of *Pasteurella trehalosi* serotypes		
T3	5×10^8	cells
T4	5×10^8	cells
T10	5×10^8	cells
T15	5×10^8	cells

Adjuvants:

Aluminium hydroxide gel	400	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
Maleic Acid	
Trometamol	
Sodium Chloride	
Formaldehyde	

Water for injections	

Opaque suspension.

3. CLINICAL INFORMATION

3.1 Target species

Sheep and lambs from 3 weeks of age.

3.2 Indications for use for each target species

For the active immunisation of sheep to reduce mortality and clinical signs of pulpy kidney, tetanus, braxy and blackleg caused by *Clostridium perfringens* type D, *Cl. tetani*, *Cl. septicum*, and *Cl. chauvoei* and to reduce mortality and clinical signs of pneumonic and systemic pasteurellosis.

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

Duration of immunity: There are reports that active immunity to the pasteurella component will last for up to one year. Active immunity to the clostridial diseases is expected to persist for up to one year.

Ovivac P Plus has been developed following research and development which resulted in the application of new 'IRP' technology for the manufacture of the pasteurella components of these vaccines. 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 full benefit of the 'IRP'.

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 due to the possible immunological incompetence of the very young lamb and competition from any maternally derived antibodies.

Sheep are very sensitive to contamination of the injection site (which may result in non-product related tissue reactions and even in abscesses). Follow strict aseptic injection techniques. Also see section 3.9.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

In the case of accidental self-injection or ingestion, 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 and lambs from 3 weeks of age:

Common (1 to 10 animals / 100 animals treated):	Injection site swelling[1]
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Elevated temperature[2] Hypersensitivity reaction

[1] Temporary, lasting for up to 3– 4 months after vaccination. Typically, may be warm when compared to the surrounding area for up to 14 days after vaccination. Safety studies in lambs have shown that the swellings did not appear to inconvenience the animals or hinder neck movement.
[2] Minor (approximately 1 °C– 2 °C) lasting for up to 1 week may occur following vaccination of lambs.

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 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 and fertility:

Can be used during pregnancy provided dosing is completed 4 - 6 weeks prior to predicted lambing date. However, the veterinary medicinal product is not recommended as a breeding stock vaccine due to the lack of a lamb dysentery component.

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

Subcutaneous use.

Dose: 2 ml.

The vaccine bottle must be shaken well before use.

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

Primary vaccination course

Two injections, each of 2 ml, separated by an interval of 4 – 6 weeks.

Revaccination

A 2 ml booster injection at intervals of not more than 12 months.

On farms where the incidence of pasteurellosis is high, a supplementary 2 ml booster injection using

Ovipast Plus may be required 2 – 3 weeks prior to expected seasonal outbreaks.

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 syringes should be noted and care should be taken to ensure the delivery of the full dose, particularly with the final doses from the bottle.

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 at least 20 minutes. No alcohol or other disinfectants should be used for sterilisation.

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

Accidental overdose is unlikely to cause any reaction other than those described in section 3.6.

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

Pharmacotherapeutic Group: Immunologicals for ovidae, Clostridium and Pasteurella.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product.

5.2 Shelf life

Shelf-life of the 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

Cardboard box with one LDPE bottle containing 100 ml (50 doses) or 500 ml (250 doses), closed with a combination cap of aluminium fitted with a rubber disc or rubber stopper.

Pack sizes:
Cardboard box containing 1 x 100 ml or 1 x 500 ml bottle.

Not all pack sizes may be marketed.

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

Medicines should not be disposed of via wastewater or household waste.

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 Ireland Ltd.

7. MARKETING AUTHORISATION NUMBER(S)

VPA10996/149/001

8. DATE OF FIRST AUTHORISATION

21/03/2003

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

02/07/2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product not subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (*https://medicines.health.europa.eu/veterinary*).