Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

OVIVAC P PLUS

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substances		per ml
Clostridium perfringens type D, strain 603 epsilon toxoid	inducing	≥ 5 IU
Clostridium septicum S1110/85 toxoid	inducing	≥ 2.5 IU
Clostridium tetani, strain 51123/91 toxoid	inducing	≥ 2.5IU
Clostridium chauvoei cells and equivalent toxoid of strains 655,656,657,658, 1048.	inducing	≥ 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
Adjuvant		
Aluminium hydroxide gel	400	mg
Excipients		
Thiomersal (preservative)	0.067 - 0.15	mg

For the full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Suspension for injection

4 CLINICAL PARTICULARS

4.1 Target Species

Sheep and lambs from 3 weeks of age.

4.2 Indications for use, specifying the 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.

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

4.3 Contraindications

None.

4.4 Special warnings for each target species

Ovivac P Plus 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.

Only vaccinate healthy animals.

4.5 Special precautions for use

Special precautions for use in animals
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 4.9.

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.

4.6 Adverse reactions (frequency and seriousness)

Vaccination may result in temporary swellings at the injection site lasting for up to 3 – 4 months after vaccination. Typically, these swellings 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.
Minor temperature increases (approximately 1 °C – 2 °C) lasting for up to 1 week may occur following vaccination of lambs.
Occasionally hypersensitivity reactions may occur.

4.7 Use during pregnancy, lactation or lay

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

4.8 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.

4.9 Amounts to be administered and administration route

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.

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

Accidental overdose is unlikely to cause any reaction other than those described in section 4.6.

4.11 Withdrawal Period(s)

Zero days.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

ATCvet code: QI04AB05
Pharmacotherapeutic Group: Immunologicals for ovidae, Clostridium and Pasteurella.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Aluminium hydroxide
Thiomersal
Maleic Acid
Trometamol
Sodium Chloride
Formaldehyde
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 immediate packaging: 10 hours.

6.4 Special precautions for storage

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

6.5 Nature and composition of immediate packaging

Carton 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.

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

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 Ireland Ltd.
Magna Drive
Magna Business Park
Citywest Road
Dublin 24

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10996/149/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 21st March 2003
Date of last renewal: 20th March 2008

10 DATE OF REVISION OF THE TEXT

December 2015