

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Ovipast Plus

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substances:

per ml

Formalin killed cells of the following
Mannheimia haemolytica strains:

A1 (S1006/77)	5 x 10 ⁸ cells*
A2 (S1126/92)	5 x 10 ⁸ cells*
A6 (S1084/81)	5 x 10 ⁸ cells*
A7 (S1078/81)	5 x 10 ⁸ cells*
A9 (S994/77)	5 x 10 ⁸ cells*

* Inducing at least 22 % OD reduction, measuring transferrin binding inhibition in rabbit sera

Formalin killed cells of the following
Pasteurella trehalosi strains:

T3 (S1109/84)	5 x 10 ⁸ cells**
T4 (S1085/81)	5 x 10 ⁸ cells**
T10 (S1075/81)	5 x 10 ⁸ cells**
T15 (S1105/84)	5 x 10 ⁸ cells**

** Inducing a significant (p<0.05) OD increase, determining antibody response in rabbit sera

Adjuvant:

Aluminium hydroxide gel 250 mg

Excipients

Preservative:

Thiomersal 0.13 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 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 pneumonic and systemic pasteurellosis in sheep.

The vaccine may be used in pregnant ewes to provide passive immunisation of their lambs to reduce mortality and clinical signs of pasteurellosis in their lambs provided that the lambs receive sufficient colostrum during the first 1-2 days of life.

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 will last for up to 12 months and that passive immunity will persist for up to 4 weeks after birth in lambs from ewes vaccinated with conventional Pasteurella vaccines.

Ovipast 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 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.

4.3 Contraindications

None.

4.4 Special warnings for each target species

Do not vaccinate unhealthy animals.

When handling pregnant animals, stress should be avoided, particularly during the later stages of pregnancy.

4.5 Special precautions for use

i) Special precaution(s) for use in animals

None.

ii) 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.

iii) Other precautions

None.

4.6 Adverse reactions (frequency and seriousness)

Immunisation 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.

Occasional hypersensitivity reactions may occur.

4.7 Use during pregnancy, lactation or lay

Can be used during pregnancy.

4.8 Interaction with other medicinal products and other forms of interaction

No information is available on the compatibility of this vaccine with any other. Therefore the safety and efficacy of this product when used with any other (either when used on the same day or at different times) has not been demonstrated.

4.9 Amounts to be administered and administration route

The vaccine bottle must be shaken well before use.

Dose: 2.0 ml

Administration: subcutaneous injection in the lateral side of the upper neck observing aseptic precautions.

Basic immunisation

All sheep and lambs from 3 weeks of age must receive two injections, each of 2.0ml, separated by an interval of 4-6 weeks. In adult breeding ewes, the second 2 ml injection should be administered 4 - 6 weeks prior to lambing.

Re-vaccination scheme

A 2 ml booster injection at 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 prior to lambing.

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

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.

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 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.

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

Accidental overdosage 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

ATC Vet Code: QI04AB02

Pharmacotherapeutic Group: Immunologicals for ovidae, Pasteurella.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Aluminium hydroxide gel
Trometamol
Formaldehyde
Thiomersal
Maleic acid
Sodium chloride
Water for injections

6.2 Incompatibilities

Do not mix with any other 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) and 500 ml (250 doses). The bottles are closed with a rubber disc (Intervet UK Ltd) or rubber stopper (Laboratorios Intervet, Salamanca) with aluminium overseal combination cap.

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

Any unused veterinary medicinal product or waste material derived from such veterinary medicinal product 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 No. 10996/147/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

23rd October 2007

10 DATE OF REVISION OF THE TEXT

June 2012