

## **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 <sup>8</sup> cells*
A2 (S1126/92)	5 x 10 <sup>8</sup> cells*
A6 (S1084/81)	5 x 10 <sup>8</sup> cells*
A7 (S1078/81)	5 x 10 <sup>8</sup> cells*
A9 (S994/77)	5 x 10 <sup>8</sup> 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 <sup>8</sup> cells**
T4 (S1085/81)	5 x 10 <sup>8</sup> cells**
T10 (S1075/81)	5 x 10 <sup>8</sup> cells**
T15 (S1105/84)	5 x 10 <sup>8</sup> cells**

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

Adjuvant:

Aluminium hydroxide gel 250 mg

Excipients:

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.

#### **4.2 Indications for use, specifying the target species**

For active the immunisation of sheep as an aid in the control of pasteurellosis caused by *M.haemolytica* and *P.trehalosi*. The vaccine maybe 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.

The vaccine may be used in pregnant ewes as an aid in the control of pasteurellosis in their lambs provided that the lambs receive sufficient immune colostrum during the first 1-2 days of life.

#### **4.3 Contraindications**

None.

#### **4.4 Special warnings**

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.

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.

#### **4.5 Special precautions for use**

##### **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 intercurrent infection or metabolic disorder. As with most killed vaccines, significant levels of immunity cannot be expected until two weeks after the second dose vaccine in the primary vaccination course.

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.

##### **ii. Special precautions to be taken by the person administering the veterinary medicinal product to animals**

The vaccine bottle must be shaken well before use. Do not freeze. Syringes and needles must be from gamma-irradiated packs or freshly sterilised by boiling for a 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.

Partly used packs must be destroyed at the end of a day's operations, as re-puncture of the rubber cap could cause contamination of the remaining contents.

#### **4.6 Adverse reactions (frequency and seriousness)**

The vaccine contains an adjuvant and, as with most adjuvanted vaccines, immunisation may result in temporary swellings at the injection site. 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.

As with all vaccines, occasional hypersensitivity reactions may occur.

#### **4.7 Use during pregnancy, lactation or lay**

Ewes may be vaccinated during pregnancy as an aid in the control of pasteurellosis in their lambs provided that the lambs receive sufficient immune colostrum during the first 1-2 days of life.

#### **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 should be administered by subcutaneous injection in the lateral side of the upper neck observing aseptic precautions. All sheep not previously vaccinated with Ovipast Plus must receive two injections, each of 2.0ml, separated by an interval of 4-6 weeks. Thereafter they must receive booster injections 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 pre-lambing, as an aid in the control of pasteurellosis in their lambs.

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

The use of automatic vaccination equipment is recommended. 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.

Evidence of efficacy of the Pasteurella/Mannheimia component of Heptavac P Plus was generated in an experimental infection model 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.

Heptavac P Plus, Ovivac P Plus and Ovipast Plus have been developed following research and development which resulted in the application of new 'IRP' technology for the manufacture of the Pasteurella/Mannheimia 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 the full benefit of the 'IRP'.

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

Accidental overdosage is unlikely to cause any reaction other than described in point 4.6. No adverse local reactions were noted in overdose studies performed in pregnant ewes and lambs. A mild febrile responses was noticed in some lambs that received an overdose.

#### **4.11 Withdrawal period**

Zero days.

### **5. IMMUNOLOGICAL PROPERTIES**

To stimulate active immunity against pasteurellosis in sheep.

**ATC vet code:** QI04AB02

### **6. PHARMACEUTICAL PARTICULARS**

#### **6.1 List of excipients**

Aluminium hydroxide gel  
Thiomersal

#### **6.2 Incompatibilities**

Do not mix with any other veterinary medicinal product.

#### **6.3 Shelf-life**

3 years  
Once opened, use of the vaccine should be completed within 10 hours. Partially used containers must be discarded at the end of each day's operations.

#### **6.4 Special precautions for storage**

Store at +2°C to +8°C in the dark. Do not freeze. Use before the expiry date printed on the pack.

#### **6.5 Nature and composition of immediate packaging**

The containers are being made of low density polyethylene of 100 and 500ml volume.

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

Partly used and empty packs, syringes and needles must be disposed of in accordance with the requirements for clinical waste.

### **7. MARKETING AUTHORISATION HOLDER**

Intervet UK Ltd  
Walton Manor  
Walton  
Milton Keynes  
Buckinghamshire  
MK7 7AJ

### **8. MARKETING AUTHORISATION NUMBER**

**Vm** 01708/4401

### **9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

**Date:** 27 November 1996 / 22 February 2006

### **10. DATE OF REVISION OF THE TEXT**

**Date:** March 2012

#### **Prohibition of sale, supply and/or use**

Not applicable