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:	
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 International B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
Netherlands

8. MARKETING AUTHORISATION NUMBER

Vm 06376/4118

9. DATE OF FIRST AUTHORISATION

27 November 1996

10. DATE OF REVISION OF THE TEXT

November 2024

Approved 18 November 2024
Gavin Hall