SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ovipast Plus suspension for injection for sheep

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml of vaccine contains:

Active substances:
Mannheimia haemolytica:
Serotype A1, strain S1006/77, Inactivated 5 x 10^8 cells*
Serotype A2, strain S1126/92, Inactivated 5 x 10^8 cells*
Serotype A6, strain S1084/81, Inactivated 5 x 10^8 cells*
Serotype A7, strain S1078/81, Inactivated 5 x 10^8 cells*
Serotype A9, strain S994/77, Inactivated 5 x 10^8 cells*
* Inducing at least 22% OD reduction, measuring transferrin binding inhibition in rabbit sera.

Bibersteinia trehalosi:
Serotype T3, strain S1109/84, Inactivated 5 x 10^8 cells**
Serotype T4, strain S1085/81, Inactivated 5 x 10^8 cells**
Serotype T10, strain S1075/81, Inactivated 5 x 10^8 cells**
Serotype T15, strain S1105/84, Inactivated 5 x 10^8 cells**
** Inducing a significant ($p<0.025$) OD increase, determining antibody response in rabbit sera.

Adjuvants:
Aluminium hydroxide gel 250 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	0.13 mg
TRIS	
Maleic acid	
Sodium chloride	
Formaldehyde	
Water for injections	

Opaque suspension.

3. CLINICAL INFORMATION

3.1 Target species

Sheep.

3.2 Indications for use for each target species

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

Onset of immunity: As with most inactivated vaccines, significant levels of immunity cannot be expected until 2 weeks after the second dose vaccine in the primary vaccination course.

Duration of immunity: Evidence of efficacy of the Pasteurella/Mannheimia component was generated in an experimental infection model using Heptavac P Plus 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 1 year and that passive immunity will persist for up to 4 weeks after birth in lambs from ewes vaccinated with conventional Pasteurella vaccines.

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 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.

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.

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.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
In case of accidental self-injection, 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:

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

[1] May be present for up to 3-4 months post-vaccination. They do not appear to inconvenience the animals or hinder neck movement.
[2]Typically associated with swelling and up to 14 days after vaccination.

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 its local representative 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:
Can be used during pregnancy in 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.

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

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 this vaccine must receive two injections, each of 2.0 ml, 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 this vaccine may be required 2-3 weeks prior to expected seasonal outbreaks.

The vaccine bottle must be shaken well before use.

Strict precautions should be taken against contamination of the vaccine. The vaccine must 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 a least 20 minutes.

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.

Partially used containers must be discarded at the end of each day's operations, as re puncture of the rubber cap could cause contamination of the remaining contents.

This vaccine has been developed following research and development which resulted in the application of new ‘IRP’ technology for the manufacture of the Pasteurella/Mannheimia components in this 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. Studies on the response of sheep to this vaccine show that two injections separated by an interval of 4-6 weeks are required to gain the full benefit of the ‘IRP’.

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

After administration of 2-fold dose of the vaccine, no adverse events other than those mentioned in section 3.6 Adverse events were observed.

A mild febrile response was noticed in some lambs that received an overdose.

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: QI04AB02.

To stimulate active immunity against pasteurellosis in sheep.

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: use within 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

Low density polyethylene bottle of 100 ml and 500 ml with chlorobutyl rubber closure and aluminium cap.

Pack sizes:
Cardboard box containing 1 bottle of 100 ml or 500 ml.
Not all pack sizes may be marketed.

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

Medicines should not be disposed of via wastewater.

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 International B.V.

7. MARKETING AUTHORISATION NUMBER

Vm 06376/4118

8. DATE OF FIRST AUTHORISATION

27 November 1996

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

May 2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

Approved 04 August 2025

Gavin Hall