PARTICULARS TO APPEAR ON THE OUTER PACKAGE – CARDBOARD BOX – 1 x 100 ml or 1 x 500 ml bottle

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ovipast Plus suspension for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml of vaccine contains:

Active substances:

*M. haemolytica**, serotypes A1, A2, A6, A7, A9, Inactivated 5 x 10^8 cells/strain
*B. trehalosi***, serotypes T3, T4, T10, T15, Inactivated 5 x 10^8 cells/strain

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

** inducing a significant ($p<0.025$) OD increase, determining antibody response in rabbit sera

Adjuvants:

Aluminium hydroxide gel 250 mg

3. PACKAGE SIZE

100 ml
500 ml

4. TARGET SPECIES

Sheep.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Subcutaneous use.

7. WITHDRAWAL PERIODS

Withdrawal periods: Zero days.

8. EXPIRY DATE

Exp. {mm/yyyy}
Once broached use within 10 hours.

9. SPECIAL STORAGE PRECAUTIONS

Store in a refrigerator.
Do not freeze.
Protect from light.

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

11. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

12. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Intervet International B.V.

Distributor in Northern Ireland:
Intervet Ireland Ltd.

14. MARKETING AUTHORISATION NUMBER

Vm 06376/4118

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE – PLASTIC BOTTLE LABEL (bottle with 100 ml or 500 ml)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ovipast Plus suspension for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml of vaccine contains:

Active substances:

*M. haemolytica**, serotypes A1, A2, A6, A7, A9, Inactivated 5 x 10^8 cells/strain
*B. trehalosi***, serotypes T3, T4, T10, T15, Inactivated 5 x 10^8 cells/strain

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

** inducing a significant ($p<0.025$) OD increase, determining antibody response in rabbit sera

Adjuvants:

Aluminium hydroxide gel 250 mg

100 ml
500 ml

3. TARGET SPECIES

Sheep.

4. ROUTES OF ADMINISTRATION

Subcutaneous use.
Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal periods: Zero days.

6. EXPIRY DATE

Exp. {mm/yyyy}

Once broached use within 10 hours.

7. SPECIAL STORAGE PRECAUTIONS

Store in a refrigerator.
Do not freeze.
Protect from light.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Intervet International B.V.

9. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Ovipast Plus suspension for injection for sheep

2. Composition

Each ml of vaccine contains:

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

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

Adjuvants:
Aluminium hydroxide gel 250 mg

Excipients:
Thiomersal 0.13 mg

Opaque suspension.

3. Target species

Sheep.

4. Indications for use

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.

5. Contraindications

None.

6. Special warnings

Special warnings:
Vaccinate healthy animals only.

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.

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.

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.

Overdose:
After administration of 2-fold dose of the vaccine, no adverse events other than those mentioned in section 7 were observed.

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

Special restrictions for use and special conditions for use:
Not applicable.

Major incompatibilities:
Do not mix with any other veterinary medicinal product.

7. 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 product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or its local representative using the contact details at the end of

this leaflet, or via your national reporting system: Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine
e-mail: adverse.events@vmd.gov.uk.

8. Dosage for each species, routes and method of administration

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.

9. Advice on correct administration

The vaccine bottle must be shaken well before use.

Strict precautions should be taken against contamination of the vaccine. Use sterile syringes and needles.
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.

10. Withdrawal periods

Zero days.

11. Special storage precautions

Keep out of the sight and reach of children.

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

Do not use this veterinary medicinal product after the expiry date which is stated on the label after Exp. The expiry date refers to the last day of that month.

Shelf life after first opening the immediate packaging: use within 10 hours.

12. Special precautions for disposal

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 applicable national collection systems. These measures should help to protect the environment.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation number and pack sizes

Vm 06376/4118

Pack sizes:
Cardboard box with 1 bottle of 100 ml or 500 ml.

Not all pack sizes may be marketed.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

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

16. Contact details

Marketing authorisation holder:
Intervet International B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
Netherlands

Manufacturer responsible for batch release[1]:
Intervet International B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
The Netherlands

MSD Animal Health UK Ltd.
Walton Manor, Walton, Milton Keynes
Buckinghamshire, MK7 7AJ
United Kingdom

Local representative:
MSD Animal Health UK Limited
Walton Manor, Walton,
Milton Keynes, MK7 7AJ, United Kingdom

Contact details to report suspected adverse events:
UK(GB)
MSD Animal Health UK Ltd.
Tel.: +44 (0)1908 685685

UK(NI)
Intervet Ireland Ltd.
Tel.: +353 (0)1 2970220

Distributor in Northern Ireland:
Intervet Ireland Ltd.
Magna Drive, Magna Business Park
Citywest Road, Dublin 24, Ireland

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

17. Other information

POM-VPS

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

[1] The printed package leaflet will state the name and address of the manufacturer responsible for the release of the concerned batch only.

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'.

Approved 04 August 2025

Gavin Hall