PARTICULARS TO APPEAR ON THE OUTER PACKAGE – Cardboard box – for the 100 ml or 500 ml bottle

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ovivac P Plus suspension for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml of vaccine contains:
Cl. perfringens ε toxoid ≥ 5 IU, *Cl. septicum* toxoid ≥ 2.5 IU, *Cl. tetani* toxoid ≥ 2.5 IU, *Cl. chauvoei* ≥ 0.5 guinea pig PD_{90}, *M. haemolytica* and *P. trehalosi* 5 x 10^8 cells/strain

3. PACKAGE SIZE

100 ml (50 doses)
500 ml (250 doses)

4. TARGET SPECIES

Sheep.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Subcutaneous use.

7. WITHDRAWAL PERIODS

Withdrawal period: Zero days.

8. EXPIRY DATE

Exp. {mm/yyyy}

Once broached use within 10 hours.

9. SPECIAL STORAGE PRECAUTIONS

Store in a refrigerator (2 °C – 8 °C.
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

MA Holder:
Intervet International B.V.

Distributor in Northern Ireland:
Intervet Ireland Ltd.

14. MARKETING AUTHORISATION NUMBER

Vm 06376/4119

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE – Bottle label
(bottle with 100 ml or 500 ml)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ovivac P Plus suspension for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:
Cl. perfringens ε toxoid ≥ 5 IU, *Cl. septicum* toxoid ≥ 2.5 IU, *Cl. tetani* toxoid ≥ 2.5 IU, *Cl. chauvoei* ≥ 0.5 guinea pig PD_{90}, *M. haemolytica* and *P. trehalosi* 5 x 10^8 cells/strain

100 ml (50 doses)
500 ml (250 doses)

3. TARGET SPECIES

Sheep.

4. ROUTES OF ADMINISTRATION

Read the package leaflet before use.
Subcutaneous 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 (2 °C – 8 °C).
Do not freeze.
Protect from light.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

MA 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

Ovivac P Plus suspension for injection for sheep

2. Composition

Each ml of vaccine contains:

Active substances:

Clostridium perfringens type D, strain 603 ε toxoid	≥ 5 IU
Clostridium septicum, strain S1110/85 toxoid	≥ 2.5 IU
Clostridium tetani, strain 51123/91 toxoid	≥ 2.5 IU
Clostridium chauvoei, strains 655, 656, 657, 658, 1048 cells and equivalent toxoid	≥ 0.5 guinea pig PD_{90} * per strain
Mannheimia haemolytica, strains A1, A2, A6, A7, A9	5 x 10^8 cells per strain
Pasteurella trehalosi, strains T3, T4, T10, T15	5 x 10^8 cells per strain

* PD_{90} = protective dose 90% survival.

Adjuvant:

Aluminium hydroxide gel	350 mg

Excipient:

Thiomersal	0.067 - 0.15 mg

Opaque suspension.

3. Target species

Sheep.

4. Indications for use

For the active immunisation of sheep as an aid in the control of pulpy kidney, tetanus, braxy, and blackleg caused by *Cl. perfringens* type D, *Cl. septicum*, *Cl. tetani* and *Cl. chauvoei*.
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.

Onset of immunity: As with most killed vaccines, significant levels of immunity cannot be expected until two weeks after the second dose of 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 one 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 veterinary medicinal product should not be used in lambs less than 3 weeks of age.
Should this vaccine be used in breeding stock, 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.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
In the case of accidental self-injection seek medical advice immediately and show the package leaflet or the label to the physician.

Pregnancy:
Ewes may be vaccinated during pregnancy as an aid in the control of pulpy kidney, tetanus and pasteurellosis in their lambs provided that the lambs receive sufficient immune colostrum during the first 1 - 2 days of life. However, this vaccine is not recommended as a breeding stock vaccine due to the lack of a lamb dysentery component. The combined 7 in 1 clostridial plus pasteurella vaccine, Heptavac P Plus, is the recommended breeding stock vaccine since it provides optimal aid in the control of the predominant clostridial diseases in adult sheep by active immunisation and in young lambs by passive immunisation.

Should the veterinary medicinal product be used as a breeding stock vaccine, 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.

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:
Accidental overdosage is unlikely to cause any reaction other than described in section "Adverse events". No adverse local or systemic reactions were noted in overdose studies performed in lambs.

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 reaction[1]
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Hypersensitivity reaction

[1] 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.

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 the local representative of the marketing authorisation holder 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

Dose: Sheep of all ages: 2 ml.

Administration: Subcutaneous use.
The vaccine should be administered by subcutaneous injection in the lateral side of the upper neck observing aseptic precautions.

All lambs not previously vaccinated with the veterinary medicinal product must receive two injections, each of 2 ml, separated by an interval of 4 - 6 weeks. Thereafter they must receive booster injections at intervals of not more than 12 months.

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

The veterinary medicinal product should not be used in lambs less than 3 weeks of age due to the possible immunological incompetence of the very young lamb and competition from any maternally derived colostral antibodies. Lambs born to Heptavac P Plus vaccinated ewes will, provided they receive sufficient immune colostrum during the first 1 - 2 days of life, have adequate initial levels of antibody to aid in the control of lamb dysentery, pulpy kidney, tetanus and pasteurellosis.
To maintain aid in the control of pulpy kidney, tetanus and pasteurellosis, lambs being retained for late fattening or storing will require a full vaccination course of Ovivac P Plus. At a minimum age of 3 weeks these lambs should receive two injections, each of 2 ml, separated by an interval of 4 - 6 weeks.

Lambs being retained for subsequent breeding will require a full course of vaccination with a suitable breeding stock vaccine. The combined 7 in 1 Clostridial plus Pasteurella vaccine, Heptavac P Plus, is the recommended breeding stock vaccine since it provides optimal aid in the control of the predominant clostridial diseases in adult sheep by active immunisation and in young lambs by passive immunisation.

9. Advice on correct administration

The vaccine bottle must be shaken well before use.
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 20 minutes.
It is recommended that an automatic vaccinator is used. Since the bottle containing this product is non-collapsible the vaccinator must have a vented draw-off spike or similar device. 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.
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. The expiry date refers to the last day of that month.

Shelf life after first opening the immediate packaging: 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.
Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Vm 06376/4119

Pack sizes:
Cardboard box containing 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 Limited
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 reactions:
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.

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

17. Other information

For the immunisation of sheep as an aid in the control of clostridial diseases and pasteurellosis. This vaccine has been developed following research and development which resulted in the application of the '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. 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 full benefit of the 'IRP'.

POM-VPS Veterinary medicinal product subject to prescription.

Gavin Hall

Approved: 22 September 2025