PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Outer Carton

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ovivac P Plus

with IRP technology

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Content per ml:

Cl. perfringens ε toxoid ≥ 5 IU, *Cl. septicum* toxoid ≥ 2.5 IU, *Cl. tetani* toxoid ≥ 2.5 IU, *Cl. chauvoei* ≥ 0.5 guinea pig PD90, *M.haemolytica* and *P. trehalosi* $5x10^8$ cells/strain, Aluminiumhydroxide 350 mg and Thiomersal 0.067 - 015 mg.

3. PHARMACEUTICAL FORM

Suspension for injection.

4. PACKAGE SIZE

100 ml

500 ml

50 x 2ml doses

250 x 2ml doses

5. TARGET SPECIES

Target Species: Sheep.

6. INDICATION(S)

For the immunisation of sheep as an aid in the control of pulpy kidney, tetanus, braxy, blackleg and pasteurellosis.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Route: subcutaneous injection.

8. WITHDRAWAL PERIOD

Withdrawal period: Zero days.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP end of:

In-use shelf life: 10 hours

11. SPECIAL STORAGE CONDITIONS

Store in a refrigerator (2 °C - 8 °C).

Protect from light.

Do not freeze.

Keep container in the outer carton.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Read the package leaflet before use.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

[Distribution category]

For animal treatment only.

POM-VPS

To be supplied only on veterinary prescription.

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

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

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

16. MARKETING AUTHORISATION NUMBER

Vm 06376/4119

17. MANUFACTURER'S BATCH NUMBER

Batch No.:

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING

Bottle Label

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ovivac P Plus

with IRP technology

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Per ml: *Cl. perfringens* ≥ toxoid - 5 IU, *Cl. septicum* toxoid ≥ 2.5 IU, *Cl. tetani* toxoid ≥ 2.5 IU, *Cl. chauvoei* ≥ 0.5 guinea pig PD90, *M. haemolytica* and *P. trehalosi* $5x10^8$ cells/strain.

3. PHARMACEUTICAL FORM

Suspension for injection.

4. PACKAGE SIZE

100 ml

500 ml

50 x 2ml doses

250 x 2ml doses

5. TARGET SPECIES

Target Species: Sheep.

6. INDICATION(S)

Not applicable.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Route: SC injection.

8. WITHDRAWAL PERIOD

Withdrawal period: Zero days.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP end of:

Once opened use within 10 hours.

11. SPECIAL STORAGE CONDITIONS

Store in a refrigerator (2 °C - 8 °C).

Protect from light.

Do not freeze.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Read the package leaflet before use.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

[Distribution category]

For animal treatment only.

POM-VPS

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

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

16. MARKETING AUTHORISATION NUMBER

Vm 06376/4119

17. MANUFACTURER'S BATCH NUMBER

Batch No.:

Directions for Use

Ovivac P Plus

When starting the Ovivac P Plus vaccination programme, two doses of vaccine must be given 4-6 weeks apart…

…thereafter, a single booster dose is required annually.

PACKAGE LEAFLET FOR:

Ovivac P Plus

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

MA 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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ovivac P Plus

Suspension for injection.

3. STATEMENT OF THE ACTIVE SUBSTANCE (S) AND OTHER INGREDIENTS

Active ingredient per ml:

Cl. perfringens type D, strain 603 ε toxoid inducing	≥ 5 IU
Cl. septicum, strain S1110/85 toxoid inducing	≥ 2.5 IU
Cl. tetani, strain 51123/91 toxoid inducing	≥ 2.5 IU

Cl. chauvoei, strains 655, 656, 657, 658, 1048

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

cells and equivalent toxoid inducing	≥ 0.5 guinea pig PD90 * per strain
M. haemolytica, strains A1, A2, A6, A7, A9	5 x 10^8 cells per strain
P.trehalosi, strains T3, T4, T10, T15	5 x 10^8 cells per strain

* PD90 = protective dose 90% survival

Adjuvant: Aluminium hydroxide	350 mg
Preservative: Thiomersal	0.067 - 0.15 mg

4. INDICATION(S)

For the active immunisation of sheep as an aid in the control of pulpy kidney, tetanus, braxy, and blackleg caused by the above listed organisms.

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.

5. CONTRAINDICATIONS

None.

6. ADVERSE REACTIONS

Occasional hypersensitivity reactions may occur. 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.

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Sheep.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Dose: Sheep of all ages: 2ml

Administration: 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 Ovivac P Plus 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. Ovivac P Plus 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 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. No alcohol or other disinfectants should be used for sterilisation.

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.

10. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Store in a refrigerator (2 ºC - 8 ºC).

Protect from light.

Do not freeze.

Do not use after the expiry date printed on the pack.

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

Partially used containers must be discarded at the end of each day‘s operations.

Keep container in the outer carton.

11. SPECIAL WARNING(S)

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 of vaccine in the primary vaccination course.Should Ovivac P Plus 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.

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.

Use during pregnancy

Although not recommended, 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.

Interactions

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.

Do not mix with any other veterinary medicinal product.

Overdose

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

12. WITHDRAWAL PERIOD(S)

Zero days.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with the local requirements.

14. 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.

15. OTHER INFORMATION

For animal treatment only.

For the immunisation of sheep as an aid in the control of clostridial diseases and pasteurellosis.Evidence of efficacy of the Pasteurella component of Ovivac 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 where adequate colostrum intake occurs.Heptavac P Plus, Ovivac P Plus and Ovipast Plus have been developed following research and development which resulted in the application of the 'IRP' technology for the manufacture of the Pasteurella 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 full benefit of the 'IRP'.Should Ovivac P Plus be used as a breeding stock vaccine, the nutritional metabolic status of pregnant ewes is extremely important at the time of vaccination. If in doubt consult your veterinary surgeon for advice.

Pack sizes

Carton with one LDPE bottle containing 100ml or 500ml closed with a combination seal.

Not all pack sizes may be marketed.

Legal category

POM-VPS

To be supplied only on veterinary prescription.

MA number: Vm 06376/4119

Distributor in Northern Ireland:

Intervet Ireland Ltd.
Magna Drive
Magna Business Park
Citywest Road
Dublin 24

Approved 18 November 2024
Gavin Hall