SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF VETERINARY MEDICINAL PRODUCT

Ovivac P Plus

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active ingredients	**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	cells and equivalent toxoid inducing ≥ 0.5 guinea pig PD_{90} * 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

* PD_{90} = protective dose 90% survival

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

For a full list of excipient 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 the active immunisation of lambs 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.

4.3 Contraindications

None

4.4 Special warnings for each target species

Ovivac P Plus should not be used in lambs less than 3 weeks of age.
Should Ovivac P Plus 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.

4.5 Special precautions for use

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 of vaccine in the primary vaccination course.

Special precautions to be taken by the person administering the 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.

4.6 Adverse reactions (frequency and seriousness)

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.

4.7 Use during pregnancy, lactation or lay

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.
Although, the vaccine may be safely used in pregnant ewes as an aid in the control of pulpy kidney, tetanus and pasteurellosis in their lambs, the vaccine contains no lamb dysentery component and therefore control of this important disease cannot be achieved by its use. Use of Ovivac P Plus as a breeding stock vaccine is therefore not recommended. 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 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.

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

Dose : 2 ml
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 vaccination with Ovipast Plus (Pasteurella vaccine) 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.

Evidence of efficacy of the Pasteurella 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 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 the full benefit of the ‘IRP’.

The vaccine bottle must be shaken well before use. Do not freeze.

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.

4.10 Overdose (symptoms, emergency procedures, antidotes) (if necessary)

Accidental overdosage is unlikely to cause any reaction other than described in section 4.6. No adverse local or systemic reactions were noted in overdose studies performed in lambs.

4.11 Withdrawal periods

Zero days.

5. IMMUNOLOGICAL PROPERTIES

ATC Vet code QI04AB05
For the immunisation of sheep as an aid in the control of clostridial diseases and pasteurellosis.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Thiomersal
Aluminium hydroxide
Tris
Maleic Acid
Sodium Chloride
Formaldehyde
Purified Water

6.2 Incompatibilities

Do not mix with any other veterinary medicinal products.

6.3 Shelf-life

Shelf life of veterinary medicinal product as packaged for sale: 3 years
Shelf life after first opening the immediate packaging: 10 hours.
Partially used containers must be discarded at the end of each day's operations.

6.4 Special precautions for storage

Store in a refrigerator (2 °C - 8 °C). Protect from light. Do not freeze.
Use before the expiry date printed on the pack.

6.5 Nature and composition of immediate packaging

Carton with one LDPE bottle containing 100 ml or 500 ml closed with a combination seal.
Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste material, derived from the use of such product if appropriate

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

7. MARKETING AUTHORISATION HOLDER

MSD Animal Health UK Limited
Walton Manor
Walton
Milton Keynes
Buckinghamshire
MK7 7AJ

8. MARKETING AUTHORISATION NUMBER

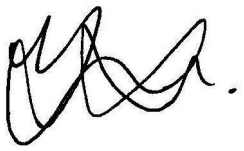
Vm 01708/4388

9. DATE OF FIRST AUTHORISATION

27 November 1996

10. DATE OF REVISION OF THE TEXT

June 2020



Approved: 02 June 2020