

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Heptavac P Plus (IT: Heptavac P)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substances:

per ml:

Clostridium perfringens beta toxoid inducing ≥ 10 IU

Clostridium perfringens epsilon toxoid inducing ≥ 5 IU

Clostridium septicum toxoid inducing ≥ 2.5 IU

Clostridium tetani toxoid inducing ≥ 2.5 IU

Clostridium novyi toxoid inducing ≥ 3.5 IU

Clostridium chauvoei cells and equivalent toxoid inducing ≥ 0.5 guinea pig PD₉₀

Formalin killed cells of the epidemiologically most important serotypes of *Mannheimia haemolytica* and *Pasteurella trehalosi* grown under iron restricted conditions: 5×10^8 cells per strain

Adjuvant:

Aluminium hydroxide gel 400 mg

Excipient:

Thiomersal 0.067-0.15 mg (preservative)

For a full list of excipients, 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 sheep as an aid in the control of lamb dysentery, pulpy kidney, struck, tetanus, braxy, blackleg, black disease, clostridial metritis caused by *Clostridium perfringens* types B, C and D, *Cl.septicum*, *Cl.novyi*, *Cl.chauvoei* and *Cl.tetani*. 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 lamb dysentery, pulpy kidney, tetanus and pasteurellosis in their lambs provided that the lambs receive sufficient immune colostrum during the first 1-2 days of life.

4.3 Contraindications

None.

4.4 Special warnings for each target species

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

When handling sheep, stress should be avoided, particularly during the later stages of pregnancy when there is a risk of inducing abortion and metabolic disorders.

Because sheep are very sensitive to contamination of the injection site (which may result in non-product related tissue reactions and even in abscesses), it is advised to follow strict aseptic injection techniques.

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.

4.6 Adverse reactions (frequency and seriousness)

Occasionally hypersensitivity reactions may occur. In the event of an anaphylactic reaction appropriate treatment should be administered without delay.

Vaccination may result in small transient injection site reactions, usually characterised by swelling, possibly lasting for up to 3-4 months after vaccination.

4.7 Use during pregnancy, lactation or lay

Ewes may be vaccinated during pregnancy as an aid in the control of lamb dysentery, pulpy kidney, tetanus and pasteurellosis in their lambs provided that the lambs receive sufficient immune colostrum during the first 1-2 days of life.

Regarding the handling of pregnant sheep see also section 4.5.

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

The vaccine should be administered by subcutaneous injection in the lateral side of the upper neck observing aseptic precautions. All breeding sheep not previously vaccinated with Heptavac P Plus 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 control of disease in their lambs.

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

Heptavac 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 being retained for fattening or subsequent breeding will require a full course of vaccination. At a minimum age of 3 weeks these lambs should receive two injections, each of 2.0 ml, separated by an interval of 4-6 weeks. It should be noted that Heptavac P Plus is the recommended vaccine for breeding stock 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.

The vaccine bottle must be shaken well before use. The use of automatic vaccination equipment 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.

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 at least 20 minutes. No alcohol or other disinfectants should be used for sterilisation.

Evidence of efficacy of the Pasteurella/Mannheimia 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 has been developed following research and development which resulted in the application of Plus 'IRP' technology for the manufacture of the Pasteurella/Mannheimia components of 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'.

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 (double dose) performed in pregnant ewes and lambs.

4.11 Withdrawal period

Zero days.

5. IMMUNOLOGICAL PROPERTIES

For the immunisation of sheep as an aid in the control of clostridial diseases and pasteurellosis.

ATCvet code: QI04AB05

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Thiomersal,
Tris,
Maleic acid,
Sodium chloride,
Formaldehyde,
Water.

6.2 Incompatibilities

Do not mix with any other veterinary medicinal product.

6.3 Shelf life

Shelf-life: 24 months.

Once opened, the vaccine must be used within 10 hours.

6.4. Special precautions for storage

Store between +2°C and +8°C in the dark. Do not freeze.

6.5 Nature and composition of immediate packaging

Low density polyethylene containers of 50, 100, 250 or 500 ml with rubber closure and aluminium cap.

Not all pack sizes may be marketed.

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

Any unused product or waste materials should be disposed of in accordance with national requirements.

7. MARKETING AUTHORISATION HOLDER

Intervet UK Ltd
Walton Manor
Walton
Milton Keynes
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MK7 7AJ

8. MARKETING AUTHORISATION NUMBER

Vm 01708/4468

9. DATE OF FIRST AUTHORISATION

11 June 1997

10. DATE OF REVISION OF THE TEXT

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