SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Heptavac P Plus suspension for injection for sheep

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml of vaccine contains:

Active substances:

Clostridium perfringens beta toxoid	≥ 10 IU*
Clostridium perfringens epsilon toxoid	≥ 5 IU*
Clostridium septicum toxoid	≥ 2.5 IU*
Clostridium tetani toxoid	≥ 2.5 IU*
Clostridium novyi toxoid	≥ 3.5 IU*
Inactivated *Clostridium chauvoei*	≥ 0.5 guinea pig PD_{90}#
Inactivated *Mannheimia haemolytica* A1, A2, A6, A7, A9	$5x10^8$ cells per strain
Inactivated *Pasteurella trehalosi* T3, T4, T10, T15	$5x10^8$ cells per strain

* International Units of antitoxin, conform Ph.Eur.
# Protective Dose 90%, conform Ph.Eur.

Adjuvant:

Aluminium hydroxide gel	400 mg

Excipient:

Thiomersal	0.067-0.15 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Opaque suspension.

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.

Onset of immunity: As with most inactivated vaccines, significant levels of immunity cannot be expected until 2 weeks after the second dose of vaccine in the primary vaccination course.

Duration of immunity: Evidence of efficacy of the Pasteurella/Mannheimia component of this vaccine 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 1 year and that passive immunity will persist for up to 4 weeks after birth in lambs from ewes vaccinated with conventional Pasteurella vaccines.

4.3 Contraindications

None.

4.4 Special warnings for each target species

Vaccinate healthy animals only.

4.5 Special precautions for use

Special precautions for use in animals
This vaccine 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.

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 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
Accidental self-injection might result in localized swelling, severe pain, soft tissue injury or infection.

In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

Special precautions for the protection of the environment
Not applicable.

Other precautions
Not applicable.

4.6 Adverse reactions (frequency and seriousness)

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, anaphylaxis[2].

[1] Small and transient. Usually characterised by swelling. May be present for up to 3-4 months post-vaccination.
[2] Sometimes fatal. If such reaction occurs, appropriate treatment should be administered without delay.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

4.7 Use during pregnancy, lactation or lay

Pregnancy:
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.

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 Amount(s) 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. Syringes and needles should be sterile before use and the injection should be made through an area of clean, dry skin taking precautions against contamination.

All breeding 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 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.

This vaccine 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 this vaccine 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.
Strict precautions should be taken against contamination of the vaccine. A fresh sterile needle must be 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.

This vaccine 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 those described in section 4.6. No adverse local or systemic reactions were noted in overdose studies (2-fold overdose) performed in pregnant ewes and lambs.

4.11 Withdrawal period(s)

Zero days.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Immunologicals for *ovidae*, sheep, inactivated bacterial vaccines (including mycoplasma, toxoid and chlamydia), clostridium and pasteurella.

ATCvet 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
Tris
Maleic acid
Sodium chloride
Formaldehyde
Water

6.2 Major incompatibilities

Do not mix with any other veterinary medicinal product.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after first opening the immediate packaging: use within 10 hours.

6.4 Special precautions for storage

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

6.5 Nature and composition of immediate packaging

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

Pack sizes:
Cardboard box containing 1 bottle of 50 ml, 100 ml, 250 ml or 500 ml.

Not all pack sizes may be marketed.

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

Medicines should not be disposed of via wastewater.

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

7. MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER

Vm 06376/5020

9. DATE OF FIRST AUTHORISATION

11 June 1997

10. DATE OF REVISION OF THE TEXT

January 2025

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.

11. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

Find more product information by searching for the 'Product Information Database' or 'PID' on www.gov.uk.

Gavin Hall
Approved: 08 January 2025