1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Heptavac P Plus suspension for injection for sheep

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1 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

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Thiomersal	0.067 - 0.15 mg
Tris	
Maleic acid	
Sodium chloride	
Formaldehyde	
Water	

Opaque suspension.

3. CLINICAL INFORMATION

3.1 Target species

Sheep and lambs from 3 weeks of age.

3.2 Indications for use for each target species

For the active immunisation of sheep to reduce mortality and clinical signs of lamb dysentery, pulpy kidney, struck, tetanus, braxy, blackleg and black disease, caused by *Clostridium perfringens* types B, C and D, *Cl. septicum, Cl. novyi, Cl. chauvoei* and *Cl. tetani*.
For the active immunisation of sheep to reduce mortality and clinical signs of pneumonic and systemic pasteurellosis.
For use in pregnant ewes to provide passive immunisation of their lambs to reduce mortality and clinical signs of lamb dysentery, pulpy kidney, tetanus and pasteurellosis in their lambs provided that the lambs receive sufficient colostrum during the first 1 – 2 days of life.

Onset of immunity: Significant levels of immunity cannot be expected until two weeks after the second dose of vaccine in the primary vaccination course.

Duration of immunity: There are reports that active immunity will last for up to 12 months and that passive immunity will persist for up to 4 weeks after birth in lambs from ewes vaccinated with conventional pasteurella vaccines.

Active immunity to the clostridial diseases is expected to persist for up to one year with passive immunity being present up to 3 weeks after birth of lambs from vaccinated ewes.

3.3 Contraindications

None.

3.4 Special warnings

Vaccinate healthy animals only.

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.

3.5 Special precautions for use

Special precautions for safe use in the target species:
Sheep are very sensitive to contamination of the injection site (which may result in non-product related tissue reactions and even in abscesses). Follow strict aseptic injection techniques. Also see section 3.9.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Accidental self-injection might result in localised swelling, severe pain, soft tissue injury or infection. In the case of accidental self-injection or ingestion 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.

3.6 Adverse events

Sheep:

Common (1 to 10 animals / 100 animals treated):	Injection site swelling[1].
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Hypersensitivity reaction. Elevated temperature[2]

[1]May be present for up to 3-4 months post-vaccination. Typically, these swellings may be warm when compared to the surrounding area for up to 14 days after vaccination. Safety studies in lambs have shown that the swellings did not appear to inconvenience the animals or hinder neck movement.
[2] Minor (approximately 1 °C – 2 °C) and lasting for up to 1 week may occur following vaccination of lambs.

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 the national competent authority via the national reporting system. See the last section of the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy:
Can be used during pregnancy.
Stress should be avoided when vaccinating pregnant animals, particularly during the later stages of pregnancy.

3.8 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.

3.9 Administration routes and dosage

Dose: 2 ml
Administration route: Subcutaneous use in the lateral side of the upper neck observing aseptic precautions.

Primary vaccination course

Breeding sheep
All breeding sheep must receive two injections, each of 2 ml, separated by an interval of 4 – 6 weeks. In adult breeding ewes, the second 2 ml dose should be administered 4 – 6 weeks prior to lambing.

Lambs
Lambs retained for fattening or subsequent breeding require a full course of vaccination. 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.

Revaccination
A 2 ml booster injection at intervals of not more than 12 months. In adult breeding ewes these yearly booster injections should be given 4 – 6 weeks prior to lambing.
On farms where the incidence of pasteurellosis is high, a supplementary 2 ml booster injection using the veterinary medicinal product or Ovipast Plus may be required 2 – 3 weeks prior to expected seasonal outbreaks.

The vaccine bottle must be shaken well before use.

Administer the vaccine using a sterile needle and syringe.
Use a fresh sterile needle 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.
The use of an automatic vaccinator is recommended. Since the bottle is non-collapsible, a vaccinator with a vented draw-off spike or similar device must be used. Follow the instructions supplied with such syringes and care should be taken to ensure the delivery of the full dose, particularly with the final few doses from the bottle.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

Accidental overdosage is unlikely to cause any reaction other than those described in section 3.6.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Zero days.

4. IMMUNOLOGICAL INFORMATION

4.1 ATCvet code: QI04AB05

Clostridium and Pasteurella vaccine for the immunisation of sheep as an aid in the control of clostridial diseases and pasteurellosis.

The veterinary medicinal product has been developed following research and development which resulted in the application of Plus 'IRP' technology for the manufacture of the pasteurella 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.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product.

5.2 Shelf life

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

5.3 Special precautions for storage

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

5.4 Nature and composition of immediate packaging

Carboard box with one LDPE bottle containing 50 ml (25 doses), 100 ml (50 doses), 250 ml (125 doses) or 500 ml (250 doses). The bottles are closed with a rubber disc/aluminium overseal combination cap.

Not all pack sizes may be marketed.

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

Medicines should not be disposed of via wastewater or household waste.

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 national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Intervet Ireland Limited.

7. MARKETING AUTHORISATION NUMBER(S)

VPA10996/146/001

8. DATE OF FIRST AUTHORISATION

21/03/2003

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

30/08/2024

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product not subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database: (https://medicines.health.europa.eu/veterinary).