Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Heptavac P Plus

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	≥ 2.5IU
Clostridium novyi toxoid	inducing	≥ 3.5 IU
Clostridium chauvoei cells and equivalent toxoid of strains 655,656,657,658, 1048.	inducing	≥ 0.5 guinea pig PD_{90}
Formalin killed cells of *Mannheimia haemolytica* serotypes:		
A1	5×10^8	cells
A2	5×10^8	cells
A6	5×10^8	cells
A7	5×10^8	cells
A9	5×10^8	cells
Formalin killed cells of *Pasteurella trehalosi*serotypes:		
T3	5×10^8	cells
T4	5×10^8	cells
T10	5×10^8	cells
T15	5×10^8	cells
Adjuvant		
Aluminium hydroxide gel	400	mg
Excipients		
Thiomersal (preservative)	0.067 - 0.15	mg

For the full list of excipients see section 6.1

3 PHARMACEUTICAL FORM

Suspension for injection

4 CLINICAL PARTICULARS

4.1 Target Species

Sheep and lambs from 3 weeks of age.

4.2 Indications for use, specifying the 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*. The vaccine may also be used for the active immunisation of sheep to reduce mortality and clinical signs of pneumonic and systemic pasteurellosis.
The vaccine may be used 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.

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

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 approximately 3 weeks after birth in lambs from ewes vaccinated with Heptavac P Plus.
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 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

4.3 Contraindications

None.

4.4 Special warnings for each target species

Only vaccinate healthy animals
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.

4.5 Special precautions for use

Special precautions for use in animals
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 4.9.

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

4.6 Adverse reactions (frequency and seriousness)

Vaccination may result in temporary swellings at the injection site lasting for up to 3 – 4 months after 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.
Minor temperature increases (approximately 1°C – 2°C) lasting for up to 1 week may occur following vaccination of lambs.
Occasionally hypersensitivity reactions may occur.

4.7 Use during pregnancy, lactation or lay

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

4.8 Interaction with other medicinal products and other forms of 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.

4.9 Amounts to be administered and administration route

Dose: 2 ml
Administration: Subcutaneous injection 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 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 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 Ovipast Plus may be required 2 – 3 weeks prior to expected seasonal outbreaks.

The vaccine bottle must be shaken well before use

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.

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. 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 those described in section 4.6.

4.11 Withdrawal period(s)

Zero days.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Immunologicals for ovidae; inactivated bacterial vaccines; Clostridium and Pasteurella.
ATCvet code: QI04AB05

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Aluminium hydroxide
Thiomersal
Maleic acid
Trometamol
Sodium chloride

Formaldehyde
Water for injections

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: 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

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

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

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

7 MARKETING AUTHORISATION HOLDER

Intervet Ireland Limited
Magna Drive
Magna Business Park, Citywest Road
Dublin 24
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA10996/146/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 21 March 2003
Date of last renewal: 20 March 2008

10 DATE OF REVISION OF THE TEXT

August 2021