LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Heptavac P Plus

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

per ml:
Cl.perfringens beta toxoid inducing ≥ 10 IU
Cl.perfringens epsilon toxoid inducing ≥ 5 IU
Cl.septicum toxoid inducing ≥ 2.5 IU
Cl.tetani toxoid inducing ≥ 2.5 IU
Cl.novyi toxoid inducing ≥ 3.5 IU
Cl.chauvoei cells and equivalent toxoid inducing ≥ 0.5 guinea pig PD90
Formalin killed cells of the epidemiologically most important serotypes of *M. haemolytica* and *P. trehalosi*: 5x108 cells per strain
Al-hydroxide gel, Thiomersal

3. PHARMACEUTICAL FORM

Suspension for injection.

4. PACKAGE SIZE

1 x 50 ml, 1 x 100 ml, 1 x 250 ml and 1 x 500 ml.

5. TARGET SPECIES

Sheep.

6. INDICATION(S)

Vaccine against clostridial diseases and pasteurellosis.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Subcutaneous injection.

Read the package leaflet before use. [Comment: mentioned on the packaging itemonly once.]

8. WITHDRAWAL PERIOD

Withdrawal period: Zero days.

9. SPECIAL WARNING(S), IF NECESSARY

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

Read the package leaflet before use. [Comment: mentioned on the packaging itemonly once.]

10. EXPIRY DATE

EXP {month/year}
Once opened use within 10 hours.

11. SPECIAL STORAGE CONDITIONS

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

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Read the package leaflet before use. [Comment: mentioned on the packaging itemonly once.]

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only.

14. THE WORDS “KEEP OUT OF THE REACH AND SIGHT OF CHILDREN”

Keep out of the reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

MSD Animal Health UK Ltd.
Walton Manor, Walton
Milton Keynes
MK7 7AJ

16. MARKETING AUTHORISATION NUMBER(S)

Vm 01708/4468

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON IMMEDIATE PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Heptavac P Plus

2. STATEMENT OF ACTIVE SUBSTANCE(S)

per ml:
Cl.perfringens β toxoid ≥ 10 IU, ε toxoid ≥ 5 IU, *Cl.septicum* toxoid ≥ 2.5 IU, *Cl.tetani* toxoid ≥ 2.5 IU, *Cl.novyi* toxoid ≥ 3.5 IU, *Cl.chauvoei* ≥ 0.5 guinea pig PD90, *M. haemolytica* and *P. trehalosi*: 5x108 cells/strain

3. PACKAGE SIZE

50 ml
100 ml
250 ml
500 ml

4. TARGET SPECIES

Sheep.

5. ROUTE(S) OF ADMINISTRATION

s.c. injection

6. WITHDRAWAL PERIOD

Withdrawal period: Zero days.

7. SPECIAL WARNING(S), IF NECESSARY

Read package leaflet before use.

8. EXPIRY DATE

EXP {month/year}

Once opened use within 10 hours.

9. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

10. MANUFACTURER’S BATCH NUMBER

Lot {number}

MSD logo

B. PACKAGE LEAFLET

PACKAGE LEAFLET

Heptavac P Plus

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDERAND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:
MSD Animal Health UK Ltd.
Walton Manor, Walton
Milton Keynes
Buckinghamshire
MK7 7AJ

Manufacturer responsible for the batch release[1]:
Intervet International BV
Wim de Körverstraat 35
5831 AN Boxmeer, The Netherlands

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Heptavac P Plus

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

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 PD_{90}
Formalin killed cells of the epidemiologically most important serotypes of *Mannheimia haemolytica* and *Pasteurella trehalosi* grown under iron restricted conditions: $5x10^8$ cells per strain
Al-hydroxide gel, Thiomersal

[1] The printed package leaflet will state the name and address of the manufacturer responsible for the release of the concerned batch only.

4. INDICATION(S)

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.

5. CONTRAINDICATIONS

None.

6. ADVERSE REACTIONS

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.

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Sheep.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

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.

9. ADVICE ON CORRECT ADMINISTRATION

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.
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.

10. WITHDRAWAL PERIOD

Zero days.

11. SPECIAL STORAGE PRECAUTIONS

Store between +2°C and +8°C in the dark. Do not freeze. Once opened, the vaccine must be used within 10 hours. Do not use after the expiry date stated on the label.

12. SPECIAL WARNING(S)

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.

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.

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.

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.

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.

Do not mix with any other veterinary medicinal product.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIAL, IF ANY

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

June 2021

15. OTHER INFORMATION

Low density polyethylene containers of 50, 100, 250 or 500 ml with rubber closure and aluminium cap.
Not all pack sizes may be marketed.

Inactivated bacterial vaccine for the immunisation of sheep as an aid in the control of clostridial diseases and pasteurellosis. ATCvet code: QI04AB05

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’

Approved 21 February 2022