LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ovipast Plus

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Per 1 ml: 5 x 10^8 killed cells each of *M. haemolytica* strains A1, A2, A6, A7, A9* and *P. trehalosi* strains T3, T4, T10, T15**
* inducing at least 22% OD reduction, measuring transferrin binding inhibition in rabbit sera
** inducing a significant ($p<0.05$) OD increase, determining antibody response in rabbit sera

Aluminium hydroxide gel, Thiomersal

3. PHARMACEUTICAL FORM

Suspension for injection

4. PACKAGE SIZE

100 ml, 500ml

5. TARGET SPECIES

Sheep

6. INDICATION(S)

Vaccine against pasteurellosis caused by *M. haemolytica* and *P. trehalosi*

7. METHOD AND ROUTE OF ADMINISTRATION

s.c. injection of 2 ml
Read package leaflet before use

8. WITHDRAWAL PERIOD

Withdrawal period: Zero days

9. EXPIRY DATE

EXP:
Once broached use within 10 hours

10. SPECIAL STORAGE CONDITIONS

Store at 2°C to 8°C in the dark. Do not freeze.

11. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only

12. THE WORDS "KEEP OUT OF THE REACH AND SIGHT OF CHILDREN"

Keep out of the reach and sight of children

13. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

Distributor in Northern Ireland:
Intervet Ireland Ltd.
Magna Drive,
Magna Business Park,
Citywest Road,
Dublin 24

14. MARKETING AUTHORISATION NUMBER

Vm 01708/4401

15. MANUFACTURER'S BATCH NUMBER

Lot:

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ovipast Plus

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Per 1 ml: 5 x 10^8 killed cells each of *M. haemolytica* strains A1, A2, A6, A7, A9* and *P. trehalosi* strains T3, T4, T10, T15**
* inducing at least 22% OD reduction, measuring transferrin binding inhibition in rabbit sera
** inducing a significant ($p<0.05$) OD increase, determining antibody response in rabbit sera

3. PHARMACEUTICAL FORM

Suspension for injection

4. PACKAGE SIZE

100 ml, 500ml

5. TARGET SPECIES

Sheep

6. ROUTE OF ADMINISTRATION

s.c. injection of 2ml
Read package leaflet before use

7. WITHDRAWAL PERIOD

Withdrawal period: zero days

8. EXPIRY DATE

EXP: .....
Once broached use within 10 hours

9. SPECIAL STORAGE CONDITIONS

Store at 2°C to 8°C in the dark. Do not freeze.

10. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only

11. NAME OF THE MARKETING AUTHORISATION HOLDER

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

12. MANUFACTURER'S BATCH NUMBER

Lot. .....

PACKAGE LEAFLET

Ovipast Plus

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND 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 batch release[1]:
Intervet International BV
Wim de Körverstraat 35
5831 AN Boxmeer
The Netherlands

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ovipast Plus

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

Per 1 ml:
5 x 10^8 formalin killed cells each of *M. haemolytica* strains A1 (S1006/77), A2 (S1126/92), A6 (S1084/81), A7 (S1078/81), A9 (S994/77), inducing at least 22% OD reduction, measuring transferrin binding inhibition in rabbit sera;
5 x 10^8 formalin killed cells each of *P. trehalosi* strains T3 (S1109/84), T4 (S1085/81), T10 (S1075/81), T15 (S1105/84), inducing a significant ($p<0.05$) OD increase, determining antibody response in rabbit sera.
Aluminium hydroxide gel, Thiomersal

4. INDICATION(S)

For active the immunisation of sheep as an aid in the control of pasteurellosis caused by *M. haemolytica* and *P. trehalosi*. The vaccine maybe used as an aid in the control of pneumonic pasteurellosis in sheep of all ages

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

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 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

The vaccine contains an adjuvant and, as with most adjuvanted vaccines, immunisation may result in temporary swellings at the injection site. 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.
As with all vaccines, occasional hypersensitivity reactions may occur.

7. TARGET SPECIES

Sheep

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

Subcutaneous injection in the lateral side of the upper neck
All sheep not previously vaccinated with Ovipast Plus must receive two injections, each of 2.0ml, 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 the control of pasteurellosis in their lambs.
On farms where the incidence of pasteurellosis is high, a supplementary booster vaccination with Ovipast Plus may be required 2-3 weeks prior to expected seasonal outbreaks.

9. ADVICE ON CORRECT ADMINISTRATION

When handling sheep, stress should be avoided, particularly during the later stages of pregnancy when there is a risk of inducing metabolic disorders which may lead to abortion.
The vaccine bottle must be shaken well before use. Do not freeze.
Use sterile syringes and needles. 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 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.

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.
Do not mix with any other veterinary medicinal product.

10. WITHDRAWAL PERIOD

Zero days

11. SPECIAL STORAGE PRECAUTIONS

Store at +2^{o}C - +8^{o}C in the dark. Do not freeze.
Once broached use within 10 hours

12. SPECIAL WARNING(S)

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.

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

Partly used and empty packs, syringes and needles must be disposed of in accordance with the requirements for clinical waste.

14. DATE ON WHICH THE PACKAGE INSERT WAS LAST APPROVED

October 2020

15. OTHER INFORMATION

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 vaccine in the primary vaccination course. 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, Ovivac P Plus and Ovipast Plus have been developed following research and development which resulted in the application of new ‘IRP’ technology for the manufacture of the Pasteurella/Mannheimia components of these vaccines. 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 these vaccines show that two injections separated by an interval of 4-6 weeks are required to gain the full benefit of the 'IRP'.

For animal treatment only.

Pack sizes: 100 or 500 ml.
Not all pack sizes may be marketed.

Keep out of the reach and sight of children

Marketing Authorisation number:

Vm 01708/4401

Legal category

POM-VPS
To be supplied only on veterinary prescription

Distributor in Northern Ireland:
Intervet Ireland Ltd.
Magna Drive
Magna Business Park
Citywest Road
Dublin 24

Approved 01 October 2020