PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Louping-ill Vaccine

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

per dose (1 ml):

Inactivated Louping-ill virus 6.7 MLD_{50} – 9.0 MLD_{50}

Thiomersal 0.085 – 0.115 mg

3. PHARMACEUTICAL FORM

Emulsion for Injection

4. PACKAGE SIZE

20 ml

5. TARGET SPECIES

Sheep.

6. INDICATION(S)

For vaccination of sheep against Louping-ill

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Dose: Sheep 1 ml

For subcutaneous injection

8. WITHDRAWAL PERIOD

Withdrawal period: Zero days.

9. SPECIAL WARNING(S), IF NECESSARY

Accidental injection of this vaccine in humans can cause serious localised reactions.

Read package leaflet before use.

10. EXPIRY DATE

Use by:

After first opening the containers, the contents should be used immediately.

11. SPECIAL STORAGE CONDITIONS

Store in a refrigerator

(2 °C – 8 °C).

Do not freeze.

Protect from light.

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

Read package leaflet before use.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE *[Distribution category]*

For animal treatment only.

POM-VPS

To be supplied only on veterinary prescription

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

Keep out of the reach and sight of children

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

MA holder

Intervet UK Ltd.

Walton Manor

Walton

Milton Keynes

Bucks MK7 7AJ

Distributor in Northern Ireland

Intervet Ireland Ltd.

Magna Drive

Magna Business Park

Citywest Road

Dublin 24

16. MARKETING AUTHORISATION NUMBER(S)

MA number: Vm 01708/4555

17. MANUFACTURER'S BATCH NUMBER

Lot

PARTICULARS TO APPEAR ON THE THE IMMEDIATE PACKAGE

Label

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Louping-ill Vaccine

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

INACTIVATED LOUPING-ILL VIRUS 6.7 – 9.0 MLD_{50} per ml

3. PHARMACEUTICAL FORM

Emulsion for Injection

4. PACKAGE SIZE

20 ml

5. TARGET SPECIES

Sheep.

6. INDICATION(S)

For vaccination of sheep against Louping-ill

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Dose: 1 ml,

Shake well.

For subcutaneous injection.

8. WITHDRAWAL PERIOD

READ PACKAGE LEAFLET BEFORE USE

9. SPECIAL WARNING(S), IF NECESSARY

Accidental injection of this vaccine in humans can cause serious localised reactions – see package leaflet.

10. EXPIRY DATE

Use by:

11. SPECIAL STORAGE CONDITIONS

FOR ANIMAL TREATMENT ONLY

STORE IN A REFRIGERATOR (2°C TO 8°C).

PROTECT FROM LIGHT.

DO NOT FREEZE.

KEEP THE CONTAINER IN THE OUTER CARTON

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

READ PACKAGE LEAFLET BEFORE USE

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE *[Distribution category]*

FOR ANIMAL TREATMENT ONLY

POM-VPS

To be supplied only on veterinary prescription

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

KEEP OUT OF THE SIGHT AND REACH OF CHILDREN

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

MA holder

Intervet UK Ltd.

Walton Manor

Walton

Milton Keynes

Bucks MK7 7AJ

16. MARKETING AUTHORISATION NUMBER(S)

MA number: Vm 01708/4555

17. MANUFACTURER’S BATCH NUMBER

Lot:

PACKAGE LEAFLET FOR:
Louping-ill Vaccine

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

Marketing authorisation holder

Intervet UK Ltd.

Walton Manor

Walton

Milton Keynes

Bucks. MK7 7AJ

Manufacturer for the batch release:

Burgwedel Biotech GmbH

Im Langen Felde 5

30938 Burgwedel

Germany

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Louping-ill Vaccine

White oily emulsion for injection

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

Active ingredient	**per ml**
Inactivated Louping-ill virus	6.7 – 9.0 MLD_{50}

Adjuvant

Liquid paraffin/Montanide 0.67 ml

4. INDICATION(S)

For active immunisation of sheep to stimulate an immunological response to the Louping-ill virus.

Onset of immunity: within 4 weeks of vaccination.

Duration of immunity as shown by an anamnestic response is at least 18 months.

5. CONTRAINDICATIONS

No information is available from laboratory studies on the safety of this vaccine administered during early to mid pregnancy, although experience of use in the field suggests that problems are unlikely to occur. Animals should not be vaccinated within the last month of gestation.

6. ADVERSE REACTIONS

Local reactions at the injection site are anticipated in the majority of animals after vaccination due to the oil adjuvant in the vaccine. Non-painful dermal thickening and swelling may produce a local reaction of up to 5 x 10 cm approximately 2-3 weeks after vaccination. The reaction will persist but slowly resolve over a 4-5 week period. Some loss of wool may occur at the injection site. No information on microscopic features of the injection site reactions is available.

Note: These observations were noted after administration of a double dose (2 ml) of vaccine.

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

Administer a 1 ml dose by subcutaneous injection on the side of the neck.

Animals should be revaccinated after 2 years, at least 4 weeks prior to the period of greatest infection risk.

9. ADVICE ON CORRECT ADMINISTRATION

To facilitate injection, the vaccine should be removed to a warm room a few hours before use. Pre-warming of the vaccine should not exceed 37°C (blood temperature) for 30 minute or 25°C for 8 hours. Shake the container well before withdrawing the doses.

10. WITHDRAWAL PERIOD(S)

Zero days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Store in a refrigerator (2°C – 8°C).

Protect from frost.

Protect from light.

Do not use after the expiry date stated on the label and carton.

Shelf-life after first opening the container: use immediately.

12. SPECIAL WARNING(S)

Occasional hypersensitivity reactions may occur. In such case, appropriate treatment such as adrenaline should be administered without delay.

Lambs born from vaccinated ewes acquire passive antibody, via the colostrum, for the first few weeks of life.

In any animal population there may be a small number of individuals which fail to respond fully to vaccination. Successful vaccination depends upon correct storage and administration of the vaccine and the ability of the animal to respond. This can be influenced by such factors as genetic constitution, intercurrent infection, age, nutritional status, concurrent drug therapy and stress.

Special precautions for use in animals

The recommended injection site is on the side of the neck. Do not administer by intramuscular injection.

In view of the oily nature of the vaccine, very strict precautions against contamination should be taken since abscess formation may prevent satisfactory immunisation. Syringes and needles should be sterilised before use and the injection should be made through an area of clean, dry skin.

A dry day should be selected for vaccination.

Special precautions to be taken by the person administering the product to animals

To the user

This product contains mineral oil. Accidental injection/self-injection may result in severe pain and swelling, particularly if injected into a joint or finger, and in rare cases could result in the loss of the affected finger if prompt medical attention is not given.

If you are accidentally injected with this product, seek prompt medical advice even if only a very small amount is injected and take the package leaflet with you. If pain persists for more than 12 hours after medical examination, seek medical advice again.

To the physician

This product contains mineral oil. Even if small amounts have been injected, accidental

injection with this product can cause intense swelling, which may, for example, result in ischaemic necrosis and even the loss of a digit. Expert, PROMPT surgical attention is required and may necessitate early incision and irrigation of the injected area, especially where there is involvement of finger pulp or tendon.

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 decided on a case by case basis.

Do not mix with any other veterinary medicinal product.

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

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

March 2014

15. OTHER INFORMATION

To stimulate active immunity against the Louping-ill virus.

ATC vet code: QI04AA01

Pack size

25 ml clear glass vials (Ph Eur Type I) containing 20 ml vaccine, sealed with a rubber stopper and aluminium seal.

Legal Category:

POM-VPS
To be supplied only on veterinary prescription.

MA number: Vm 01708/4555

Distributor in Northern Ireland:

Intervet Ireland Ltd.

Magna Drive

Magna Business Park

Citywest Road

Dublin 24

Approved: 08/08/2017