SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE IMMUNOLOGICAL VETERINARY MEDICINAL PRODUCT

Louping Ill vaccine

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance	per ml
Inactivated Louping Ill virus (before inactivation)	6.7 MLD_{50} – 9.0 MLD_{50}
Adjuvant	
Liquid paraffin/Montanide	0.67

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Emulsion for injection.

4. CLINICAL PARTICULARS

4.1 Target species

Sheep

4.2 Indications for use, specifying the target species

For active immunisation of sheep to stimulate an immunological response to the Louping Ill virus.
Onset of immunity is within 4 weeks of vaccination and duration as shown by an anamnestic response is at least 18 months.

4.3 Contraindications

None.

4.4 Special warnings for each target species

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.

4.5 Special precautions for use

i. 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.

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

i. 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.

ii. 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.

4.6 Adverse reactions (frequency and seriousness)

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.

4.7 Use during pregnancy, lactation or lay

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.

4.8 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 decided on a case by case basis.

4.9 Amounts to be administered and administration route

Administer a 1 ml dose by subcutaneous injection on the side of the neck.
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.
Animals should be revaccinated after 2 years, at least 4 weeks prior to the period of greatest infection risk.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

See section 4.6.

4.11 Withdrawal period

Zero days.

5. IMMUNOLOGICAL PROPERTIES

To stimulate active immunity against the Louping ill virus.

ATC vet code: QI04AA01

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Thiomersal
Liquid paraffin/Montanide
Formaldehyde
Neomycin (production remnant)

6.2 Incompatibilities

Do not mix with any other veterinary medicinal product.

6.3 Shelf life

Shelf-life as packaged for sale : 24 months.
After first opening the containers, the contents should be used immediately.

6.4 Special precautions for storage

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

6.5 Nature and composition of immediate packaging

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

6.5.1 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products, if appropriate.

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

7. MARKETING AUTHORISATION HOLDER

Intervet UK Ltd.
Walton Manor
Walton
Milton Keynes
Buckinhamshire
MK7 7AJ

8. MARKETING AUTHORISATION NUMBER

Vm 01708/4555

9. DATE OF RENEWAL OF THE AUTHORISATION

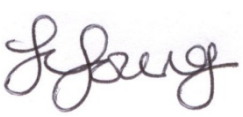
Date: 19 October 2005

10. DATE OF LAST REVISION OF TEXT

Date: April 2013

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable

Approved:  **10/05/2013**