

## Presentation

A white oil emulsion vaccine prepared from louping-ill virus grown in tissue culture, inactivated with formalin, concentrated by ultra filtration and emulsified with a mineral oil. Contains liquid paraffin/Montanide as adjuvant and thiomersal as preservative.

## Uses

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

## Contra-indications, warnings, etc

### *Warnings*

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.

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

Part-used containers of the vaccine should be disposed of safely at the end of the day's operations, as under field conditions it may be difficult to avoid accidental contamination.

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 insert 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.

### **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.

### **Interaction with other medicinal products**

No information is available on the safety and efficacy from the concurrent use of this vaccine with any other. It is therefore recommended that no other vaccines should be administered within 14 days before or after vaccination with the product.

### **Withdrawal Period:**

Zero days.

## Pharmaceutical precautions

Store between +2°C and +8°C, protected from light. Do not freeze. Protect from light.

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

Do not mix with any other medicinal product.

Keep out of the reach and sight of children.

### Disposal advice

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

### Legal category

POM-VPS (previously PML)

## Packaging Quantities

20 ml glass bottles.

### Further information

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 together with the animal's ability to respond. This can be influenced by such factors as genetic constitution, intercurrent infection, age, the presence of maternally-derived antibodies, nutritional status, concurrent drug therapy and stress.

## Marketing authorisation number

Vm 00201/4206.

## Dosage and administration

### *Dose*

1 ml.

### *Administration*

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 degrees C (blood temperature) for 30 minutes or 25 degrees 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.

### *Use during pregnancy and lactation*

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.