

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE AND THE IMMEDIATE PACKAGE {Carton/Label}**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Stellamune Mycoplasma

**2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES**

Each 2ml dose contains inactivated *Mycoplasma hyopneumoniae* at least 15272 RU (Relative ELISA units), Thiomersal (Max 0.2mg), Mineral oil (0.09ml), and Lecithin (Max 0.01ml).

**3. PHARMACEUTICAL FORM**

Emulsion for injection

**4. PACKAGE SIZE**

25, 50 or 125 dose

**5. TARGET SPECIES**

Pigs

**6. INDICATION(S) (Carton ONLY)**

For use as an aid, together with management and hygienic measures, in the control of enzootic pneumonia in fattening pigs caused by *Mycoplasma hyopneumoniae*.

**7. METHOD AND ROUTE(S) OF ADMINISTRATION**

For intramuscular injection

**8. WITHDRAWAL PERIOD**

Zero days

**9. SPECIAL WARNING(S), IF NECESSARY**

Accidental injection in humans is dangerous — See package leaflet before use

**10. EXPIRY DATE**

**11. SPECIAL STORAGE CONDITIONS**

Keep the container in the outer carton.

Store between +2°C and +8°C.

Do not freeze.

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

For full details see pack leaflet

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

POM-V

For animal treatment only. 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**

Elanco Animal Health,  
Eli Lilly and Company Ltd,  
Lilly House, Priestley Road,  
Basingstoke, Hampshire,  
RG24 9NL

**16. MARKETING AUTHORISATION NUMBER(S)**

Vm 00006/4118

**17. MANUFACTURER’S BATCH NUMBER**

**PACKAGE LEAFLET FOR:**

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

MA Holder

Elanco Animal Health,  
Eli Lilly and Company Ltd,  
Lilly House, Priestley Road,  
Basingstoke, Hampshire,  
RG24 9NL

Manufacturing Authorisation Holder responsible for batch release

Zoetis Belgium  
Rue Laid Burniat 1  
Louvain-la-Neuve  
B-1348 Belgium

Or

Elanco Animal Health Ireland Limited  
Finisklin Industrial Estate  
Sligo, Ireland

**2. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Stellamune Mycoplasma

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

**4. INDICATION(S)**

For use as an aid, together with managemental and hygienic measures, in the control of enzootic pneumonia in fattening pigs caused by *Mycoplasma hyopneumoniae*.

**5. CONTRAINDICATIONS**

The use of immunosuppressant drugs or procedures is contraindicated within one month of vaccination.

**6. ADVERSE REACTIONS**

A small proportion of animals may be unable to develop or maintain an adequate immunity following vaccination. Very occasionally, administration of the vaccine may be followed by a mild, transient reaction at the injection site. These reactions are

limited to swelling with or without redness, and mild tenderness to direct pressure. The reactions have not been observed to cause alterations of normal behaviour in affected pigs. The reactions resolve spontaneously within a few days, do not cause blemishes of the carcass at slaughter, and no remedial action need be taken.

If an anaphylactic reaction occurs, administer adrenaline or other appropriate medication.

## **7. TARGET SPECIES**

Pigs

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

2 ml administered by the deep intramuscular route, preferably behind the ear and through an area of clean dry skin, taking precautions to avoid contamination. Shake well before use. Two doses should be given to piglets. The 1st dose at one week of age and the 2nd dose 2-4 weeks later. Older pigs (3-6 weeks old) may be vaccinated against enzootic pneumonia, especially if they are to be moved from premises where the incidence of the disease is low to premises where the disease incidence is higher. In this case each pig should be vaccinated twice, with an interval between doses of 2-4 weeks, before shipping. However, it should be remembered that pigs vaccinated for the first time at more than one week of age may already have pulmonary changes due to Mycoplasma infection and that therefore, the protection conferred by vaccination may not be as strong as that seen when younger piglets are vaccinated.

## **9. ADVICE ON CORRECT ADMINISTRATION**

Shake well before use. Ensure vaccination equipment is clean and sterile before use and remains so during vaccination. Small quantities of unused product and empty vials are to be disposed of safely by burning, or by immersion in an approved disinfectant before disposal.

## **10. WITHDRAWAL PERIOD(S)**

Zero days

## **11. SPECIAL STORAGE PRECAUTIONS**

Store between +2°C and +8°C.

Do not freeze.

Keep out of the reach and sight of children

## **12. SPECIAL WARNING(S)**

## For Animal Treatment Only

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.

### **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 local requirements.

### **14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED**

*[It is recommended that the following reference to the VMD Website is included:]*

<Find more product information by searching for the 'Product Information Database' or 'PID' on [www.gov.uk](http://www.gov.uk).>

### **<15. OTHER INFORMATION>**

POM – V To be supplied only on veterinary prescription

*Vm 00006/4118*

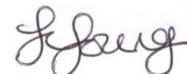
No information is available on the compatibility of this vaccine with any other. Therefore the safety and efficacy of this product when used with any other (either when used on the same day or at different times) has not been demonstrated.

PACKAGE QUANTITIES

Stellamune Mycoplasma is available in vials containing 10 doses (20ml), 50 doses (100ml) and 125 doses (250ml).

Not all pack sizes may be marketed.

**Approved: 05/01/2018**

A handwritten signature in black ink, appearing to read 'J. Jung', located below the approval date.