SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Stellamune Mycoplasma

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 2 ml dose contains:

Active ingredients
Inactivated *Mycoplasma hyopneumoniae* at least 15272 RU/2ml dose (Relative ELISA units) at release to ensure 15272 RU dose throughout shelf-life.

Excipients

Thiomersal	Max. 0.185 mg

Adjuvants

Mineral oil	Max. 0.09 ml
Lecithin	Max. 0.01 ml

For a full list of excipients, see Section 6.1

3. PHARMACEUTICAL FORM

Emulsion for injection

4. CLINICAL PARTICULARS

4.1 Target species

Pigs

4.2 Indications for use, specifying the target species

Stellamune Mycoplasma is intended for use as an aid, together with management and hygiene measures, in the control of enzootic pneumonia in fattening pigs caused by *Mycoplasma hyopneumoniae*.

4.3 Contraindications

None.

4.4 Special warnings for each target species

Vaccinate only healthy animals.
The use of immunosuppressant drugs or procedures is contraindicated within one month of vaccination.

In any animal population, a small number of individuals may fail to respond fully to vaccination.
If an anaphylactic reaction occurs, administer adrenaline or an equivalent.

4.5 Special precautions for use

i. Special precautions for use in animals

None

ii. Special precautions to be taken by the person administering the veterinary medicinal 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 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.

4.6 Adverse reactions (frequency and seriousness)

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

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.

4.7 Use during pregnancy, lactation or lay

Not applicable.

4.8 Interaction with other medicinal products and other forms of interaction

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.

4.9 Amounts to be administered and administration route

The vaccine is to be administered at the rate of 2 ml by the deep intramuscular route, preferably behind the ear and through a clean site.

Primary vaccination. Two doses should be given to piglets. The 1st dose at one week of age and the 2nd dose 2-4 weeks later.

It may be desired to vaccinate older pigs (3 – 6 weeks old) 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 piglets are vaccinated.

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

No post vaccination reactions have been observed after administration of an overdose.

4.11 Withdrawal period(s)

Zero Days

5. IMMUNOLOGICAL PROPERTIES

Active immunisation against *Mycoplasma hyopneumoniae.*
ATC Vet Code QI09AB13

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Saline solution
Thiomersal
EDTA
Polysorbate 80 (tween 80)

Sorbitan mono-oleate (Span 80)
Mineral Oil
Lecithin

6.2 Incompatibilities

None known.

6.3 Shelf-life

Shelf life of the veterinary medicinal product as packaged for sale:
3 years (10 and 50 dose vials).
1 year (125 dose vials).

6.4. Special precautions for storage

Store between +2°C and +8°C. Do not freeze.

6.5 Nature and composition of immediate packaging

10 dose in HDPE vials and glass type 1
50 dose in HDPE vials and glass type 1
125 dose in HDPE vials

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

Any unused product or waste material should be disposed of in accordance with national requirements.

7. MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER

Vm 00006/4118

9. DATE OF THE FIRST AUTHORISATION

19th February 1996

10. DATE OF REVISION OF THE TEXT

April 2015

Approved: 09 April 2015