Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

STELLAMUNE MYCOPLASMA

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 2 ml dose contains

Active Substance

Inactivated *Mycoplasma hyopneumoniae* at least 10,529 RU* at release to ensure 6000 RU* throughout shelf-life.

* = Relative ELISA Units

Adjuvants

Liquid paraffin 0.09 ml

Excipients

Thiomersal 0.185 mg

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Emulsion for injection

4 CLINICAL PARTICULARS

4.1 Target Species

Fattening pigs from one week of age.

4.2 Indications for use, specifying the target species

For active immunisation of fattening pigs to reducelung lesion scores caused by *Mycoplasma hyopneumoniae* infection.Protection against *Mycoplasma hyopneumoniae* reduces the impact of secondary bacterial infection with *Pasteurella multocida*, offering improved health and economic benefits. Immunity is acquired two weeks following the second vaccination and protection lasts throughout the fattening period.

4.3 Contraindications

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

4.4 Special warnings for each target species

Vaccinate only healthy animals.
In any animal population, a small number of individuals may fail to respond fully to vaccination.
Since Stellamune Mycoplasma is only recommended for reduction of lung lesions scores caused by *Mycoplasma hyopneumoniae* infectionit is important that all animals in a herd should be vaccinated to reduce the spread of the disease.
Use of the vaccine should be combined with high management standards to maximise the benefits of vaccination.

4.5 Special precautions for use

Special precaution(s) for use in animals

None.

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 casescould 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 ischemic 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)

Hypersensitivity reactions can occasionally occur after the administration of Stellamune Mycoplasma (tremor, vomiting, dyspnoea). These reactions on very rare occasions can result in mortality. Such reactions are more likely in piglets born to dams vaccinated during pregnancy with an oil-containing Aujeszky or Aujeszky/Influenza vaccine. However, the reported incidence of these reactions is low even in piglets born to such dams.

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

Administration of the vaccine may be followed by a mild injection site reaction. These reactions are limited to swelling (0.5-2 cm in diameter)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. Transient (7-10 days duration) temperature increases (of the order of 1°C - 2°C) can also occur post vaccination.

4.7 Use during pregnancy, lactation or lay

Not to be used during pregnancy and lactation.

4.8 Interaction with other medicinal products and other forms of interaction

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

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.

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

Shake the vial before use. Use only sterile needles and syringes for administration.

It may be desired to vaccinate older pigs (3 – 6 weeks old) against *Mycoplasma hyopneumoniae* infection, 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

Post vaccination reactions following an overdose are similar to those following a single dose (see 4.6).

4.11 Withdrawal period(s)

Zero days.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

ATC Vet code QI09AB13 To stimulate active immunisation against *Mycoplasma hyopneumoniae*.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Liquid paraffin
Soya Lecithin
Polysorbate 80
Sorbitan Mono-oleate
Thiomersal
Sodium EDTA
Buffered Saline

6.2 Major incompatibilities

Do not mix with any other medicinal product.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 3 years In use shelf-life: use immediately

6.4 Special precautions for storage

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

6.5 Nature and composition of immediate packaging

Carton containing a Type I glass vial containing 10 doses (20 ml) or 50 doses (100 ml) or a plastic bottle containing 10 doses (20 ml), 50 doses (100 ml) or 125 doses (250 ml), closed with a rubber stopper and sealed with an aluminium cap.
Not all pack sizes may be marketed.

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

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

7 MARKETING AUTHORISATION HOLDER

Elanco GmbH
Heinz-Lohmann-Strasse 4
27472 Cuxhaven
Germany

8 MARKETING AUTHORISATION NUMBER(S)

VPA22020/040/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 4th November 2002
Date of last renewal: 3rd November 2007

10 DATE OF REVISION OF THE TEXT

July 2018