SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Stellamune Once

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Per 2 ml dose:

Active substance:
Inactivated *Mycoplasma hyopneumoniae,* strain NL1042, between 4.5 and 5.2 $\log_{10}$ units*.

*ELISA Relative Potency Units by comparison with a reference vaccine.

Adjuvant:

Amphigen Base	0.025 ml
Drakeol 5 (Mineral oil)	0.075 ml

Excipient(s):

Thiomersal	0.185 mg

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Emulsion for injection
Off white, translucent, semi turbid oil in water emulsion

4. CLINICAL PARTICULARS

4.1 Target species

Fattening pigs

4.2 Indications for use, specifying the target species

For active immunisation of piglets from 3 days of age to reduce lung lesions related to infection by *Mycoplasma hyopneumoniae* in fattening animals.
Onset of immunity: 18 days following vaccination. Duration of immunity: 26 weeks following vaccination.

For active immunisation of piglets from 3 weeks of age to reduce coughing and losses in weight gain related to infection by *Mycoplasma hyopneumoniae* in fattening animals.
Onset of immunity: 3 weeks following vaccination. Duration of immunity: 23 weeks following vaccination

None

4.4 Special warnings <for each target species>

None.

4.5 Special precautions for use

Special precautions 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/selfinjection 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.

To the physician:
This product contains mineral oil. Even if small amounts have been injected, accidental injection with this oil-based 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 tissue reactions in the form of a transient swelling at the injection site (max. diameter 2.5 cm) are very common (more than 1 in 10 animals) and may last for up to 3 days

Transient increase in rectal temperature (up to 1.9°C above baseline) can be observed for up to 4 days post vaccination.

As part of the immune reaction following vaccination, inflammatory cell infiltration and/or fibrosis may occur in the muscle tissue at the injection site lasting for at least 14 days.

Hypersensitivity reactions, including shock and death may occur in very rare cases. Appropriate treatment (for example glucocorticoid intravenously or nuscularly) should be administered.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

4.7 Use during pregnancy, lactation or lay

The safety of the veterinary medicinal product has not been established during pregnancy or lactation.

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 made on a case-by-case basis.

4.9 Amounts to be administered and administration route

Shake and aseptically administer a single 2 ml injection by deep intramuscular route in the lateral neck muscle. Needle length and diameter should be adapted to the age of the animals.

Vaccination programme:
One single dose of 2 ml of vaccine should be given.

Vaccination should be performed prior to the period of risk. Infection usually occurs within the first month of life.

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

Injection site reactions observed after the administration of one overdose are similar to those following a single dose of vaccine. Very commonly (more than 1 in 10 animals), animals vaccinated with an overdose develop a palpable injection site reaction of up to 3 cm in diameter that resolves within 2 days.
A lower growth rate has been observed in animals administered a double dose of vaccine.

4.11 Withdrawal period(s)

Zero days.

5. IMMUNOLOGICAL PROPERTIES

To stimulate active immunity against *Mycoplasma hyopneumoniae* in pigs. ATC Vet Code QI09AB13.

6. PHARMACEUTICAL PARTICULARS

cipients

Thiomersal
Polysorbate 80
Sorbitan Mono-oleate
DiSodium EDTA
Phosphate buffered saline

6.2 Incompatibilities

Do not mix with any other veterinary medicinal product.

6.3 Shelf life

Shelf life of the veterinary product as packaged for sale: 3 years. Shelf life after first opening the immediate packaging: 10 hours

6.4 Special precautions for storage

Store in a refrigerator (2°C – 8°C).
Protect from light.
Do not freeze.
A slight black deposit may appear during storage.

6.5 Nature and composition of immediate packaging

High Density Polyethylene vials containing 10, 50 or 125 doses of liquid component, respectively 20, 100 or 250 ml. Chlorobutyl rubber closures.
Packaging intended for sale are: box of 10 vials of 10 doses, box of 10 vials of 50 doses and box of 4 vials of 125 doses.

Not all pack sizes may be marketed.

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

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

7. MARKETING AUTHORISATION HOLDER

Elanco Europe Ltd.
Form 2, Bartley Way
Bartley Wood Business Park
Hook
RG27 9XA
United Kingdom

8. MARKETING AUTHORISATION NUMBER

Vm 00879/4202

9. DATE OF FIRST AUTHORISATION

10 September 2001

10. DATE OF REVISION OF THE TEXT

January 2021

Approved: 19/01/21