SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Stellamune Once

Emulsion for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 2 ml dose contains:

Active substances:
Mycoplasma hyopneumoniae, strain NL1042, inactivated, between 4.5 and 5.2 log10 units*.

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

Adjuvants:

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

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Thiomersal	0.185 mg
Polysorbate 80	
Sorbitan oleate	
Disodium EDTA	
Phosphate buffered saline	

Off white, translucent, semi turbid oil in water emulsion.

3. CLINICAL INFORMATION

3.1 Target species

Pigs (for fattening)

3.2 Indications for use for each 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

3.3 Contraindications

None.

3.4 Special warnings

Vaccinate healthy animals only.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Not applicable.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

To the user:
This veterinary medicinal 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 veterinary medicinal 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 veterinary medicinal product contains mineral oil. Even if small amounts have been injected, accidental injection with this veterinary medicinal 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.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Pigs (for fattening):

Very common (>1 animal / 10 animals treated):	Injection site swelling[1]
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Injection site fibrosis[2], Injection site inflammation[2], Hypersensitivity reaction[3], Elevated Temperature[4]

[1] Up to 2.5 cm in diameter, for up to 3 days.
[2] Can persist for over 2 weeks.
[3] Including shock and death. Appropriate treatment that may include intravenous glucocorticoid or intramuscular adrenaline should be administered.
[4] Up to 1.9° C, for up to 4 days.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

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

3.8 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.

3.9 Administration routes and dosage

Shake and aseptically administer a single 2 ml injection by deep intramuscular use 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.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

Injection site reactions observed after the administration of a 2-fold 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 2-fold overdose of vaccine.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Zero days.

4. IMMUNOLOGICAL INFORMATION

4.1 ATCvet code: QI09AB13

To stimulate active immunity against *Mycoplasma hyopneumoniae* in pigs.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product.

5.2 Shelf life

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

5.3 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.

5.4 Nature and composition of immediate packaging

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

Not all pack sizes may be marketed.

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

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Elanco GmbH

7. MARKETING AUTHORISATION NUMBER

Vm 52127/3081

8. DATE OF FIRST AUTHORISATION

10 September 2001

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

November 2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

Gavin Hall
Approved: 10 November 2025