ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Stellamune One (AT, BE, DE, LU, NL)
Stellamune Once (UK(NI))
Stellamune One Vet. (DK)
Stellamune One vet. (SE)
Stellamune Uno (IT, ES)
Stellamune Mono Injection (FR)
Stellamune Monodose (PT)
Respisure 1 One (BG)

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
(Alternative: Elanco Europe Ltd)

7. MARKETING AUTHORISATION NUMBER(S)

MA numbers should be presented here. To be completed nationally.

8. DATE OF FIRST AUTHORISATION

<Date of first authorisation:> <{DD/MM/YYYY}> <{DD month YYYY}.> To be completed nationally.

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

04/2025

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).

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box – 10x50 doses
Cardboard box – 4x125 doses

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Stellamune One
Emulsion for injection.

2. STATEMENT OF ACTIVE SUBSTANCES

Each 2 ml dose contains::
Mycoplasma hyopneumoniae, strain NL1042, inactivated, between 4.5 and 5.2 $\log_{10}$ units*.
*ELISA Relative Potency Units.

3. PACKAGE SIZE

10 x 50 doses of 2 ml each
4 x 125 doses of 2 ml each

4. TARGET SPECIES

Pigs (for fattening).

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Intramuscular use.

7. WITHDRAWAL PERIODS

Withdrawal periods: Zero days.

8. EXPIRY DATE

Exp. {mm/yyyy}

Once broached use within 10 hours.

9. SPECIAL STORAGE PRECAUTIONS

Store in a refrigerator.
Protect from light.
Do not freeze.

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

11. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only:

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

{Name or company name or logo name of the marketing authorisation holder} To be completed nationally.

14. MARKETING AUTHORISATION NUMBERS

MA numbers should be presented here. To be completed nationally.

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

High Density Polyethylene vial containing 50 doses (100 ml)
High Density Polyethylene vial containing 125 doses (250 ml)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Stellamune One

Emulsion for injection.

2. STATEMENT OF ACTIVE SUBSTANCES

Each 2 ml dose contains:*Mycoplasma hyopneumoniae*, strain NL1042, inactivated, between 4.5-5.2 log10 ELISA Relative Potency Units.

3. TARGET SPECIES

Pigs (for fattening).

4. ROUTES OF ADMINISTRATION

Intramuscular use. Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal periods: Zero days:

6. EXPIRY DATE

Exp. {mm/yyyy}

Once broached use within 10 hours.

7. SPECIAL STORAGE PRECAUTIONS

Store in a refrigerator.
Protect from light.
Do not freeze.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

{Name or company name or logo name of the marketing authorisation holder} To be completed nationally.

9. BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Stellamune One
Emulsion for injection

2. 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:

Thiomersal	0.185 mg

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

3. Target species

Pigs (for fattening).

4. Indications for use

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.

5. Contraindications

None

6. Special warnings

For animal treatment only.
Vaccinate healthy animals only.

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.

Pregnancy and lactation:
The safety of the veterinary medicinal product has not been established during pregnancy and lactation.

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.

Overdose:
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.

Major incompatibilities:
Do not mix with any other veterinary medicinal product.

7. 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 product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report

any adverse events to the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system: {national system details}.

8. Dosage for each species, routes and method of administration

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 to piglets from 3 days of age.

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

9. Advice on correct administration

Avoid multiple vial broaching and the introduction of contamination during use.

10. Withdrawal periods

Zero days.

11. Special storage precautions

Keep out of the sight and reach of children.
Store in a refrigerator (2°C – 8°C).
Do not freeze.
Protect from light.

Do not use this veterinary medicinal product after the expiry date which is stated on the label after Exp. The expiry date refers to the last day of that month.
Shelf life after first opening the immediate packaging: 10 hours.
A slight black deposit may appear during storage.

12. Special precautions for disposal

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 applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

MA numbers should be presented here. To be completed nationally.

High Density Polyethylene vials containing 50 or 125 doses (respectively 100 or 250 mL). A cardboard box containing 10 vials of 50 doses or 4 vials of 125 doses.

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

04/2025

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

16. Contact details

Marketing authorisation holder and contact details to report suspected adverse events:
To be completed nationally.

Manufacturer responsible for batch release:
Laboratorios SYVA, S.A.
Calle Nicostrato Vela M15-M16,
Parque Tecnológico de León, León, 24009
Spain