ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box – 10x10 doses
Cardboard box – 10x50 doses
Cardboard box – 4x125 doses

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Stellamune Once
Emulsion for injection for pigs.

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Per 2 ml dose:Inactivated *Mycoplasma hyopneumoniae* between 4.5and 5.2 $\log_{10}$. Relative Potency Units

3. PHARMACEUTICAL FORM

Emulsion for injection.

4. PACKAGE SIZE

10x10 doses of 2 ml each
10x50 doses of 2 ml each
4 x125 doses of 2 ml each

5. TARGET SPECIES

Fattening pigs.

6. INDICATION(S)

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

7. METHOD AND ROUTE(S) 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.
Vaccination should be performed prior to the period of risk. Infection usually occurs within the first month of life.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Withdrawal period: Zero days

9. SPECIAL WARNING(S), IF NECESSARY

Accidental injection is dangerous. Read thepackage leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Once broached use within 10 hours.

11. SPECIAL STORAGE CONDITIONS

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

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only
To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

16. MARKETING AUTHORISATION NUMBER(S)

Vm 00879/4202

17. MANUFACTURER'S BATCH NUMBER

Batch Number:

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

High Density Polyethylene vial containing 10 doses (20 ml)
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 Once
Emulsion for injection for pigs

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Per 2 ml dose:
Inactivated *Mycoplasma hyopneumoniae* 4.5-5.2 $\log_{10}$ Relative Potency Units

3. PHARMACEUTICAL FORM

Emulsion for injection.

4. PACKAGE SIZE

10 doses of 2 ml (20 ml)
50 doses of 2 ml (100 ml)
125 doses of 2 ml (250 ml)

5. TARGET SPECIES

Fattening pigs

6. INDICATION(S)

For active immunisation of piglets from 3 days of age to reduce lung lesions related to infection by *Mycoplasma hyopneumoniae* in fattening animals.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Shake well before use.
For intramuscular injection in pigs.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Withdrawal period: Zero days

9. SPECIAL WARNING(S), IF NECESSARY

Accidental injection is dangerous. Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Once broached use within 10 hours.

11. SPECIAL STORAGE CONDITIONS

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

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only
To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Elanco Europe Ltd.
Hampshire

16. MARKETING AUTHORISATION NUMBER(S)

Vm 00879/4202

17. MANUFACTURER'S BATCH NUMBER

Batch Number:

B. PACKAGE LEAFLET

PACKAGE LEAFLET
Stellamune Once

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

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

Manufacturer for the batch release:

Zoetis Belgium
Rue Laid Burniat, 1
B-1348 Louvain-la-Neuve Belgium

or

Laboratorios SYVA, S.A.U.
Avda. Portugal, s/n, Parque Tecnológico de León, Parcelas 15-16, León, 24009, Spain

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Stellamune Once

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Inactivated, adjuvanted *Mycoplasma hyopneumoniae* vaccine.
An off-white translucent, semi turbid oil in water emulsion for injection. Each 2 ml dose of vaccine contains 4.5 to 5.2 Log_{10} Relative Potency Units of inactivated M. *hyopneumoniae* Strain NLI042 and 0.025 ml of Amphigen Base, 0.075 ml of Drakeol 5 (mineral oil) and 0.185 mg Thiomersal.

4. INDICATION(S)

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. ADVERSE REACTIONS

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

Hypersensitivity reactions, including shock and death may occur in very rare cases. Appropriate treatment (for example glucocorticoid intravenously or adrenaline intramuscularly) 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).

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 inform your veterinary surgeon.

7. TARGET SPECIES

Fattening pigs.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) 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 the introduction of contamination during use.

10. WITHDRAWAL PERIOD

Zero days

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Store in a refrigerator (2°C – 8°C).
Protect from light.
Do not freeze.
Do not use this veterinary medicinal product after the expiry date, which is stated on the label.
Shelf life after first opening the container: 10 hours.
A slight black deposit may appear during storage.

12. SPECIAL WARNING(S)

For animal treatment only.

Special precautions for use in animals

None.

Overdose (symptoms, emergency procedures, antidotes)

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.

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 very small amount is injected and take the package insert 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.

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.

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

Incompatibilities
Do not mix with any other veterinary medicinal product

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

January 2021

15. OTHER INFORMATION

High-density polyethylene vials containing 10, 50 or 125 doses (respectively 20, 100 or 250 mL). 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.

Approved: 26/10/21