ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE
Carton box:
1 x 100 ml (50 doses) or 250 ml (125 doses)
10 x 100 ml (50 doses) or 250 ml (125 doses)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Suvaxyn M Hyo Suspension for injection for pigs

2. STATEMENT OF ACTIVE SUBSTANCES

Each dose (2 ml) contains:
Inactivated *Mycoplasma hyopneumoniae*, strain P-5722-3 RP≥ 1

3. PHARMACEUTICAL FORM

Suspension for injection for pigs

4. PACKAGE SIZE

1 x 100 ml (50 doses)
1 x 250 ml (125 doses)
10 x 100 ml (50 doses)
10 x 250 ml (125 doses)

5. TARGET SPECIES

Pigs for fattening

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Intramuscular use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period(s): Zero days.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Once broached use immediately.

11. SPECIAL STORAGE CONDITIONS

Store and transport refrigerated.
Do not freeze. Protect from light.

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

Legal Category: POM-V
Prescription Only Medicine - Veterinarian.
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

Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

16. MARKETING AUTHORISATION NUMBER

Vm 42058/3025

17. MANUFACTURER'S BATCH NUMBER

Lot: {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

100 ml (50 doses) HDPE bottle
250 ml (125 doses) HDPE bottle

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Suvaxyn M Hyo Suspension for injection for pigs

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

One dose (2 ml) contains:
Inactivated *Mycoplasma hyopneumoniae*, strain P-5722-3 RP ≥ 1

3. PHARMACEUTICAL FORM

Suspension for injection for pigs

4. PACKAGE SIZE

100 ml (50 doses)
250 ml (125 doses)

5. TARGET SPECIES

Pigs for fattening

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

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8. WITHDRAWAL PERIOD(S)

Withdrawal period(s): Zero days.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Once broached use immediately.

11. SPECIAL STORAGE CONDITIONS

Store and transport refrigerated.
Do not freeze. Protect from light.

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

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

For animal treatment only

Legal Category: POM-V
Prescription Only Medicine - Veterinarian.
To be supplied only on veterinary prescription.

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

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

16. MARKETING AUTHORISATION NUMBER

Vm 42058/3025

17. MANUFACTURER'S BATCH NUMBER

Lot: {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET
Suvaxyn M Hyo Suspension for injection for pigs

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

Marketing authorisation holder:

Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

Manufacturer responsible for batch release:

Zoetis Manufacturing & Research Spain, S.L
C/Camprodon s/n “La Riba”
17813 Vall de Bianya Girona
SPAIN

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Suvaxyn M Hyo Suspension for injection for pigs.

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

Each dose (2 ml) contains:

Active substance:
Mycoplasma hyopneumoniae, strain P-5722-3 RP* ≥1

Adjuvant:
Carbopol 941 4 mg

Excipients:
Thiomersal 50-115 ppm

* Relative Potency unit determined by ELISA antigen quantification (in vitro potency test) of undiluted serials compared to a reference vaccine.

4. INDICATION(S)

Active immunization against *Mycoplasma hyopneumoniae* infection in pigs to reduce the frequency and severity of lung lesions.

5. CONTRAINDICATIONS

None.

6. ADVERSE REACTIONS

Rarely a slight soft swelling of about 2 cm in diameter may be observed at the site of injection., Such swelling spontaneously disappears within few days after vaccination.

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. Alternatively, you can report via your national reporting system.

7. TARGET SPECIES

Pigs for fattening.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Intramuscular use.
A dose of 2 ml must be administered intramuscularly in the neck behind the ear twice with an interval of 2 weeks, to pigs from the age of 1 week and before the age of 10 weeks.

9. ADVICE ON CORRECT ADMINISTRATION

Shake vaccine well before administration and intermittently during the process of vaccination.
It is good practice to allow the vaccine to warm to body temperature in the hand or pocket before administration, to avoid the discomfort of injection of a cold liquid.

10. WITHDRAWAL PERIOD(S)

Zero days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Store and transport refrigerated (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

carton and the vial after EXP.

Shelf-life after first opening the container: use immediately.

12. SPECIAL WARNING(S)

Special warnings for each target species:

Avoid stress in the animals around the time of vaccination.

Vaccinate only healthy animals.

Special warnings for use in animals:
Not applicable.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
In case of accidental self-injection, seek medical advice immediately and show the package insert or the label to the physician.

Pregnancy and lactation:
Not applicable.

Fertility:
Not applicable.

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 (symptoms, emergency procedures, antidotes):
The administration of an overdose may very commonly result in the same type of reaction as seen after administration of a single dose (see 6).

Incompatibilities:
Do not mix with any other vaccine or immunological product.

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

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

To be completed nationally.

15. OTHER INFORMATION

ATC vet code: QI09AB13 Inactivated bacterial vaccines - pigs.

Packaging:
Carton box containing 1 bottle of 50 or 125 doses.
Carton box containing 10 bottles of 50 or 125 doses.
Not all pack sizes may be marketed.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

Subject to prescription.

PROHIBITION OF SALE, SUPPLY AND/OR USE

Vm 42058/3025

Approved 24 November 2023