

ANNEX I
SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Suvaxyn M Hyo Suspension for injection for pigs.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose (2 ml) contains:

Active substance

Mycoplasma hyopneumoniae, strain P-5722-3 RP \geq 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.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Suspension for injection.

4. CLINICAL PARTICULARS

4.1 Target species

Pigs for fattening.

4.2 Indications for use, specifying the target species

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

4.3 Contraindications

None.

4.4 Special warnings for each target species

Avoid stress in the animals around the time of vaccination.

Vaccinate healthy animals only.

4.5 Special precautions for use

Special precautions 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.

4.6 Adverse reactions (frequency and seriousness)

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).

4.7 Use during pregnancy, lactation or lay

Not applicable as the vaccine is only recommended for pigs for fattening.

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

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.

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

The administration of an overdose may very commonly result in the same type of reaction as seen after administration of a single dose (see 4.6).

4.11 Withdrawal period(s)

Zero days.

5. IMMUNOLOGICAL PROPERTIES

The vaccine stimulates active immunity against *Mycoplasma hyopneumoniae*.
ATC vet code: QI09AB13.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Thiomersal
EDTA
Amaranth

Sodium chloride

Sodium phosphate dibasic heptahydrate

Water for injections

6.2 Major incompatibilities

Do not mix with any other veterinary medicinal product.

6.3 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale:

50-doses (100 ml) in HDPE bottles: 27 months

125-doses (250 ml) in HDPE bottles: 27 months

Shelf life after first opening the immediate packaging: use immediately.

6.4 Special precautions for storage

Store and transport refrigerated (2 °C – 8 °C).

Do not freeze.

Protect from light.

6.5 Nature and composition of immediate packaging

High density polyethylene (HDPE) bottles containing 100 ml (50 doses) or 250 ml (125 doses) of vaccine closed with chlorobutyl rubber stoppers and sealed with aluminium caps.

Pack sizes:

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.

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 products should be disposed of in accordance with the local requirements.

7. MARKETING AUTHORISATION HOLDER

Zoetis UK Limited
5th Floor, 6 St. Andrew Street
London
EC4A 3AE

8. MARKETING AUTHORISATION NUMBER(S)

Vm 42058/4137

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorization: 15/09/1995.

10. DATE OF REVISION OF THE TEXT

Date: *To be complete nationally*

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)

Mis en forme : Français (France)

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 \geq 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)

Mis en forme : Français (France)

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

To be completed nationally.

16. MARKETING AUTHORISATION NUMBER(S)

To be completed nationally.

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 \geq 1

3. PHARMACEUTICAL FORM

Suspension for injection for pigs

4. PACKAGE SIZE

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

Mis en forme : Français (France)

5. TARGET SPECIES

Pigs for fattening

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

IM

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

To be completed nationally.

16. MARKETING AUTHORISATION NUMBER(S)

To be completed nationally.

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:

To be completed nationally.

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

To be completed nationally.