SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Suvaxyn MH-One emulsion for injection for pigs *(for AT, BE, BG, CY, CZ, DE, ES, EL, HU, HR, IE, IT, LT, LU, LV, NL, PL, PT, RO, SI, SK, and UK(NI) only)*
Suvaxyn M.Hyo Mono emulsion for injection for pigs *(for FR, DK, and SE only)*

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 2 ml dose contains:

Active substance:

Inactivated *Mycoplasma hyopneumoniae*, strain P-5722-3	RP* (undiluted) ≥ 1.00

Adjuvants:

Carbopol #941	4.00 mg
Squalane**	3.24 mg

*Relative Potency unit determined by ELISA antigen quantification (*in vitro* potency test) compared to a reference vaccine.
**As component of MetaStim (that also contains Pluronic L-121 and Polysorbate 80).

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Thiomersal	0.20 mg
Sodium chloride	
Potassium chloride	
Sodium phosphate dibasic x12 H_2O	
Potassium phosphate monobasic	
Polysorbate 80	
Pluronic L-121	
EDTA Tetrasodium $2H_2O$	
Sodium Borate	
Sodium Phosphate Dibasic	
Water for injections	

Brownish-grey emulsion.

3. CLINICAL INFORMATION

3.1 Target species

Pigs.

3.2 Indications for use for each target species

For active immunisation of pigs of a minimum age of 7 days to reduce lung lesions that are caused by *Mycoplasma hyopneumoniae.*

Onset of immunity: 2 weeks.
Duration of immunity: 6 months after 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:

Avoid stress in the animals around the time of vaccination.

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

This veterinary medicinal product contains animal oil. In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Pigs:

Very common (>1 animal / 10 animals treated):	Injection site swelling[1] Shivering[2] Piloerection[2] Depression[2], Elevated temperature[2/3]
Uncommon (1 to 10 animals / 1,000 animals treated):	Anaphylactic-type reaction Neurological signs

[1]May reach 0.3 cm in diameter (palpable, but not visible) and last for up to 2 days.
[2]Within 4 hours after vaccination and spontaneously resolving within 24 hours without treatment.
[3]Body temperature increase up to 1.9°C.

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 its local representative> 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

Pregnancy and lactation:
Do not use in pregnant or lactating animals.

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

One dose (2 ml) per animal should be administered intramuscularly in the neck to pigs from the age of 7 days onwards.

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.

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

After administration of a two-fold overdose by the recommended route to 3 weeks-old pigs, no other symptoms than those described under section 3.6 “Adverse events” can be observed. However, the duration may be prolonged (body temperature increases up to 2 days and local tissue reactions up to 3 days) and the area of local tissue reactions may reach 1.0 cm in diameter. Administration of an overdose of the vaccine has not been investigated in 1 week-old piglets.

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

To be completed nationally.

3.12 Withdrawal periods

Zero days.

4. IMMUNOLOGICAL INFORMATION

4.1 ATCvet code: QI09AB13

To stimulate active immunity against *Mycoplasma hyopneumoniae.*
Post-vaccination serum antibody levels are not related to the degree of protection afforded by vaccination.

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 medicinal product as packaged for sale: 2 years.
Shelf life after first opening the immediate packaging: use immediately.

5.3 Special precautions for storage

Store and transport refrigerated (2 °C – 8 °C).
Do not freeze.
Store in the original container.
Protect from light.

5.4 Nature and composition of immediate packaging

Container: HDPE bottle.

Filling volume:125 doses (250 ml), 50 doses (100 ml), 10 doses (20 ml) of vaccine.

Closure: butyl rubber stopper with aluminium cap.

Packaging: carton box containing 1 or 10 bottles of 10, 50 or 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

To be completed nationally.

7. MARKETING AUTHORISATION NUMBER(S)

To be completed nationally.

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: *To be completed nationally.*

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

To be completed nationally.
<{MM/YYYY}>
<{DD/MM/YYYY}>
<{DD month YYYY}>

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

[AT, BE, BG, CZ, CY, DE, DK, EL, ES, FR, HR, HU, IT, LT, LU, LV, NL, PL, PT, RO, SE, SI, SK, UK(NI)]: Veterinary medicinal product subject to prescription.

[IE]: Veterinary medicinal product not subject to prescription.

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

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Label of Cardboard Carton (Bottle): 1 x 10, 50, 125 Doses
Label of 10-Pack Cardboard Carton (Bottles): 10 x 10, 50, 125 Doses

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Suvaxyn MH-One emulsion for injection.

2. STATEMENT OF ACTIVE SUBSTANCES

Each 2 ml dose contains:

Inactivated *Mycoplasma hyopneumoniae*, strain P-5722-3 RP* (undiluted) ≥ 1.00

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

3. PACKAGE SIZE

1x 10 doses
1x 50 doses
1x 125 doses
10 x 10 doses
10 x 50 doses
10 x 125 doses

4. TARGET SPECIES

Pigs.

5. INDICATIONS

To be completed nationally.

<For products not subject to veterinary prescription.>

6. ROUTES OF ADMINISTRATION

Intramuscular use.

7. WITHDRAWAL PERIODS

Withdrawal period: Zero days.

8. EXPIRY DATE

Exp. (mm/yyyy)

Once broached use immediately.

9. SPECIAL STORAGE PRECAUTIONS

Store and transport refrigerated.
Do not freeze.
Store in the original container.
Protect from light.

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

To be completed nationally.

14. MARKETING AUTHORISATION NUMBERS

To be completed nationally.

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Bottle label: 10, 50 and 125 doses

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Suvaxyn MH-One emulsion for injection.

2. STATEMENT OF ACTIVE SUBSTANCES

Each 2 ml dose contains:

Inactivated *Mycoplasma hyopneumoniae*, strain P-5722-3	RP* (undiluted) ≥ 1.00

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

10 doses
50 doses
125 doses

3. TARGET SPECIES

Pigs.

4. ROUTES OF ADMINISTRATION

Intramuscular use.
Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal period: Zero days.

6. EXPIRY DATE

Exp. (mm/yyyy)
Once broached use immediately.

7. SPECIAL STORAGE PRECAUTIONS

Store and transport refrigerated.
Do not freeze.
Store in the original container.
Protect from light.

8. 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

Suvaxyn MH-One emulsion for injection for pigs

2. Composition

Each 2 ml dose contains:

Active substance:

Inactivated *Mycoplasma hyopneumoniae*, strain P-5722-3 RP* (undiluted) ≥ 1.00

Adjuvants:

Carbopol # 941	4.00 mg
Squalane**	3.24 mg

*Relative Potency unit determined by ELISA antigen quantification (*in vitro* potency test) compared to a reference vaccine.
**As component of MetaStim (that also contains Pluronic L-121 and Polysorbate 80).

Excipients:

Thiomersal	0.20 mg

Brownish-grey emulsion.

3. Target species

Pigs.

4. Indications for use

For the active immunisation of pigs of a minimum age of 7 days to reduce lung lesions that are caused by *Mycoplasma hyopneumoniae*.

Onset of immunity: 2 weeks.
Duration of immunity: 6 months after vaccination.

5. Contraindications

None.

6. Special warnings

Special warnings:
Vaccinate healthy animals only.

Special precautions for safe use in the target species:
Avoid stress in the animals around the time of vaccination.

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

Pregnancy and lactation:
Do not use in pregnant or lactating animals.

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:
After administration of a two-fold overdose by the recommended route to 3 weeks-old pigs, no other symptoms than those described under section "Adverse events" can be observed. However, the duration may be prolonged (body temperature increases up to 2 days and local tissue reactions up to 3 days) and the area of local tissue reactions may reach 1.0 cm in diameter. Administration of an overdose of the vaccine has not been investigated in 1 week-old piglets.

Special restrictions for use and special conditions for use:
To be completed nationally.

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

7. Adverse events

Pigs:

Very common (>1 animal / 10 animals treated):
Injection site swelling[1] Shivering[2] Bristling of hairs[2] Depression[2], Elevated temperature[2/3]
Uncommon (1 to 10 animals / 1,000 animals treated):
Anaphylactic-type (severe allergic) reaction Neurological signs

[1]May reach 0.3 cm in diameter (palpable, but not visible) and last for up to 2 days.
[2]Within 4 hours after vaccination and spontaneously resolving within 24 hours without treatment.
[3]Body temperature increase up to 1.9°C.

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 < or the local representative of 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

One dose (2 ml) per animal should be administered intramuscularly in the neck to pigs from the age of 7 days onwards.

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 periods

Zero days.

11. Special storage precautions

Keep out of the sight and reach of children.

Store and transport refrigerated (2 ºC – 8 ºC).
Do not freeze.
Store in the original container.
Protect from light.
Do not use this veterinary medicinal product after the expiry date stated on the label and outer package after Exp. The expiry date refers to the last day of that month.
Shelf life after first opening the immediate packaging: use immediately.

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

[AT, BE, BG, CZ, CY, DE, DK, EL, ES, FR, HR, HU, IT, LT, LU, LV, NL, PL, PT, RO, SE, SI, SK, UK(NI)]: Veterinary medicinal product subject to prescription.

[IE]: Veterinary medicinal product not subject to prescription.

14. Marketing authorisation numbers and pack sizes

To be completed nationally.

Carton box containing 1 or 10 bottles of 10, 50 or 125 doses.

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

To be completed nationally.

<{MM/YYYY}>
<{DD/MM/YYYY}>
<{DD month YYYY}>

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 reactions>:
To be completed nationally.

Manufacturer responsible for batch release:
Zoetis Manufacturing & Research Spain S.L.
Carretera De Camprodon S/n
La Vall De Bianya
17813 Girona
Spain

<Local representatives< and contact details to report suspected adverse reactions>:>
To be completed nationally (if needed).

17. Other information

To stimulate active immunity against *Mycoplasma hyopneumoniae.*
Post-vaccination serum antibody levels are not related to the degree of protection afforded by vaccination.