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 for pigs

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Qualitative composition	Quantitative composition (per 2.0 ml dose)
Active substances:	
Inactivated *Mycoplasma hyopneumoniae*, strain P-5722-3	RP* (undiluted) ≥ 1.00
Adjuvants:	
Carbopol #941	4.00 mg
Squalane**	3.24 mg
Excipients:	
Thiomersal	0.20 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).

3. PHARMACEUTICAL FORM

Brownish-gray emulsion for injection.

4. PACKAGE SIZE

Cardboard Carton containing 1 bottle with 10, 50, 125 Doses
Cardboard Carton containing 10 bottles with 10, 50, 125 Doses

5. TARGET SPECIES

Pigs of a minimum age of 7 days.

6. INDICATION(S)

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

7. METHOD AND ROUTE(S) OF ADMINISTRATION

One dose of 2.0 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.

8. WITHDRAWAL PERIOD

Withdrawal period: Zero days

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP: (DD/MM/YYYY)
Once opened, use immediately.

11. SPECIAL STORAGE CONDITIONS

Store and transport refrigerated at 2ºC - 8ºC.
Store protected from light in the original container.
Do not freeze.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only.

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(S)

Vm: 42058/4139

17. MANUFACTURER'S BATCH NUMBER

<Batch><Lot> {number}

MINIMUM PARTICULARS TO APPEAR ON IMMEDIATE PACKAGING UNITS

Bottle label: 10, 50 and 125 doses

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Suvaxyn MH-One
Emulsion for injection for pigs

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Qualitative composition	Quantitative composition (2.0 ml dose)
Active substances:	
Inactivated *Mycoplasma hyopneumoniae*, strain P-5722-3	RP[*] (undiluted) ≥ 1.00
Adjuvants:	
Carbopol #941	4.00 mg
Squalane[**]	3.24 mg
Excipients:	
Thiomersal	0.20 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).

3. PHARMACEUTICAL FORM

Brownish-gray emulsion for injection.

4. PACKAGE SIZE

10, 50, 125 Doses (Bottle)

5. TARGET SPECIES

Pigs of a minimum age of 7 days.

6. INDICATIONS

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

7. METHOD AND ROUTE OF ADMINISTRATION

One dose of 2.0 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.

8. WITHDRAWAL PERIOD

Withdrawal period: Zero days

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP: (DD/MM/YYYY)
Once opened, use immediately.

11. SPECIAL STORAGE CONDITIONS

Store and transport refrigerated at 2ºC - 8ºC.
Store protected from light in the original container.
Do not freeze.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

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

For animal treatment only

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

Keep out of the reach and sight 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(S)

Vm: 42058/4139

17. MANUFACTURER'S BATCH NUMBER

Lot {Number}

PACKAGE LEAFLET FOR:
Suvaxyn MH-One
Emulsion 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 for the batch release:

Pfizer Olot, S.L.U.
Carretera Camprodón s/n - 'La Riba'
17813 Vall de Bianya (Girona)
Spain

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Suvaxyn MH-One
Emulsion for injection for pigs

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

Brownish-grey emulsion.

Qualitative composition	Quantitative composition (2.0 ml dose)
Active substances:	
Inactivated *Mycoplasma hyopneumoniae*, strain P-5722-3	RP* (undiluted) ≥ 1.00
Adjuvants:	
Carbopol # 941	4.00 mg
Squalane**	3.24 mg
Excipients:	
Thiomersal	0.20 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).

4. INDICATION(S)

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 following vaccination.
Duration of immunity: 6 months.

5. CONTRAINDICATIONS

Do not use in pregnant or lactating animals.

6. ADVERSE REACTIONS*

Systemic adverse reactions, such as body temperature increases (up to 1.9ºC), depression, shivering and bristling are very common at 4 hours post vaccination. These reactions resolve spontaneously within 24 hours without treatment.
Anaphylactic and neurological reactions are uncommon.
Local tissue reactions in the form of a palpable (but not visible) swelling at the injection site are very common and last for up to 2 days. The area of local tissue reactions may reach 0.3 cm in diameter.

* The frequency of possible adverse effects is defined using the following convention:
- very common (more than 1 in 10 animals displaying adverse reaction(s) during the course of one treatment)
- common (more than 1 but less than 10 animals in 100 animals)
- uncommon (more than 1 but less than 10 animals in 1,000 animals)
- rare (more than 1 but less than 10 animals in 10,000 animals)
- very rare (less than 1 animal in 10,000 animals, including isolated reports)

If you notice any side effects (especially those that are not mentioned in this leaflet), in vaccinated animals, please inform your veterinary surgeon.

7. TARGET SPECIES

Pigs of a minimum age of 7 days.

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

One dose of 2.0 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 PERIOD

Zero Days

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight of children.

Store and transport refrigerated (2ºC - 8ºC).
Protect from light.
Do not freeze.

Do not use after the expiry date stated on the label and outer package.

Shelf-life after first opening: use immediately.

12. SPECIAL WARNING(S)

Special precautions for use in animals
Administer only to animals in good health.
Avoid stress in the animals around the time of vaccination.
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.

Do not mix with any other veterinary medicinal product.

After administration of a two-fold maximum dose by the recommended route to 3 weeks-old pigs, no other symptoms than those described under “Adverse reactions” 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 precautions to be taken by the person administering the veterinary medicinal product to animals
This product contains animal oil. In case of accidental self-injection, seek medical advice immediately and show package leaflet or label to the physician.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

<15. OTHER INFORMATION>

ATC vet Code: Q109AB13
Inactivated bacterial vaccines - pigs.

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.

Approved 25 October 2019