SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Suvaxyn MH-One
Emulsion for injection for pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

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).

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Brownish-gray emulsion for injection.

4. CLINICAL PARTICULARS

4.1 Target species

Pigs of a minimum age of 7 days.

4.2 Indications for use, specifying the 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 following vaccination.
Duration of immunity: 6 months.

4.3 Contraindications

See section 4.7.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

Administer only to animals in good health.
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 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.

4.6 Adverse reactions (frequency and seriousness)*

Systemic adverse reactions, such as body temperature increases (up to 1.9°C), 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 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)

4.7 Use during pregnancy, lactation or lay

Do not use in pregnant or lactating animals.

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

One dose (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.

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

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.

4.11 Withdrawal period(s)

Zero days.

5. IMMUNOLOGICAL PROPERTIES

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

ATC vet code: Q109AB13

Inactivated bacterial vaccines – pigs.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Thiomersal
Carbopol #941

Sodium chloride
Potassium chloride
Sodium dihydrogen phosphate x 12 H2O
Potassium phosphate monobasic
Polysorbate 80
Squalane (animal oil)
Pluronic L-121
EDTA Tetrasodium 2H20
Sodium Borate
Sodium Phosphate Dibasic
Water for injections

6.2 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:

10 doses in HDPE bottles: 24 months
50 doses in HDPE bottles: 24 months
125 doses in HDPE bottles: 24 months

Shelf-life after first opening: use immediately.

6.4 Special precautions for storage

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

6.5 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.

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 materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER

Vm 42058/4139

9. DATE OF FIRST AUTHORISATION

24 October 2008

10. DATE OF REVISION OF THE TEXT

25 October 2019

Approved 25 October 2019