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 ≥ 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*.
ATCVet code: QI09AB13

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Carbopol **# 941**
Thiomersal
EDTA
Amaranth (E123)
Sodium chloride
Water for injection
Ampicillin

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

Containers: Polyethylene bottles containing: 250 ml (125 doses) and 100 ml (50 doses) of vaccine.
Closures: Butyl rubber stoppers with aluminium caps.

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
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
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KT22 7LP

8. MARKETING AUTHORISATION NUMBER

Vm 42058/4137

9. DATE OF FIRST AUTHORISATION

15 September 1995

10. DATE OF REVISION OF THE TEXT

10 January 2020

Approved 10 January 2020