Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Suvaxyn M Hyo Suspension for injection for pigs

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

	Per dose (2 ml)
Active Substance:	
Mycoplasma hyopneumoniae strain P-5722-3	RP ≥ 1.0*

Excipients:
Thiomersal50-115 ppm
*ELISA Relative Potency units by comparison with a reference vaccine having a titre of 2 x 10^9 MHDCE** per dose.***Mycoplasma hyopneumoniae* DNA cell equivalents determined by DNA fluorometry.
For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Suspension for Injection

4 CLINICAL PARTICULARS

4.1 Target Species

Feeder finishing pigs.

4.2 Indications for use, specifying the target species

Active immunization against *Mycoplasma hyopneumoniae* infection in pigs to reduce the frequency and severity of lung lesions. The onset of immunity is 1 week following the second dose and duration of immunity is at least 4½ months.

4.3 Contraindications

The vaccination of sick animals is contra-indicated.Do not vaccinate animals which have received immunosuppressive drugs until at least 4 weeks have elapsed.

4.4 Special warnings for each target species

Avoid stress in the animals around the time of vaccination.
It is advisable to vaccinate all animals in a herd in order to minimise the spread of infection.

4.5 Special precautions for use

Special precautions for use in animals

None.

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

Occasionally a soft swelling of about 2 cm in diameter may be observed at the site of injection, which will disappear within a few days.

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 feeder-finishing pigs.

4.8 Interaction with other medicinal products and other forms of interactions

No information is available on the compatibility of this vaccine with any other.Therefore the safety and efficacy of this product when used with any other (either when used on the same day or at different times) has not been demonstrated.

4.9 Amounts to be administered and administration route

1 dose= 2 ml.
Route of administration: intramuscular injection, in the neck behind the ear.

Basic vaccination scheme:
Two doses should be administered, with an interval of 2 weeks between each dose.
Vaccination should take place from the age of 1 week and before the age of 10 weeks.
Immunocompetence in the pig increases with age. Age at vaccination should be determined by consideration of the timing of field challenge. For example, earlier vaccination is recommended where early challenge is expected.

Shake vaccine well before use. Warm vaccine to body temperature before using.
When administering product from a multi-dose container, use of a multi-dosing automatic syringe is recommended.
Aseptic precautions should be observed. Syringes should not have been chemically sterilised or be above ambient temperature.

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

The administration of an overdose may 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 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

The vaccine contains *Mycoplasma hyopneumoniae*, strain P-5722-3 inactivated by L-Bromoethyleneamine Hydrobromide and adjuvanted with Carbopol. The vaccine stimulates active immunity against *Mycoplasma hyopneumoniae*, which is demonstrated by challenge.
ATCvet code: Q109AB13.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Carbopol 941
Thiomerosal

Ethylenediaminetetraacetic acid
Amaranth (E123)
Sodium ChlorideWater for Injection

6.2 Major incompatibilities

Do not mix with any other immunological product.

6.3 Shelf-life

Shelf life for bottles: 27 months.Shelf life after opening of the container: Use vaccine immediately.

6.4 Special precautions for storage

Store in arefrigerator 2°C - 8°C.
Protect from light.
Do not freeze.

6.5 Nature and composition of immediate packaging

Containers: Box with 1 or 10 polyethylene bottles containing: 125 doses (250 ml), 50 doses (100 ml) .
Closures: Butyl rubber stoppers with aluminium caps.

Not all presentations may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Any unused product or waste material should be disposed of in accordance with national requirements.

7 MARKETING AUTHORISATION HOLDER

Zoetis Belgium S.A.
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8 MARKETING AUTHORISATION NUMBER(S)

VPA10387/067/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 14 November 2002
Date of last renewal: 13 November 2007

10 DATE OF REVISION OF THE TEXT

June 2020