SUMMARY OF PRODUCT CHARACTERISTCS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Suvaxyn M.hyo – Parasuis, suspension for injection for pigs.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substances	**per 2 ml dose**
Inactivated *Mycoplasma hyopneumoniae*, strain P-5722-3	RP* 1 – 1.9
Inactivated *Haemophilus parasuis* serotype 4, strain 2170B	RP* 1 – 8.1
Inactivated *Haemophilus parasuis* serotype 5, strain IA84-29755	RP* 1 – 3.4

* Relative potency as compared to a reference in an in-vitro ELISA assay

Adjuvant:	
Carbopol 941	4.0 mg
Excipients:	
Thiomersal	0.2 mg

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Suspension for injection.
Semi-transparent, homogeneous, pale red solution

4. CLINICAL PARTICULARS

4.1 Target species

Pigs (fatteners).

4.2 Indications for use, specifying the target species

For the active immunisation of pigs to reduce lung lesions caused by *Mycoplasma hyopneumoniae* and to reduce lesions and clinical signs caused by *Haemophilus parasuis* serotypes 4 and 5.
Onset of immunity against *Mycoplasma hyopneumoniae* has been demonstrated one week after second vaccination.
Onset of immunity against *Haemophilus parasuis* serotype 4 and 5 has been demonstrated 3.5 weeks after second vaccination.
Duration of immunity studies indicate that the vaccine protects for 6 months after the second vaccination against *Mycoplasma hyopneumoniae* and *Haemophilus parasuis* serotypes 4 and 5.

4.3 Contraindications

None.

4.4 Special warnings for each target species

The efficacy of the *H. parasuis* components of the vaccine may be reduced due to maternal antibody (MDA) interference.
Field studies have shown that maternal antibody titres to *H. parasuis* have dropped significantly in most cases by 3 weeks of age.

4.5 Special precautions for use

Special precautions for use in animals

Only healthy animals should be vaccinated.

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 and show the package insert or the label to the physician.

4.6 Adverse reactions (frequency* and seriousness)

Vaccinated animals may very commonly experience a mild injection site reaction (up to 3.7 cm in diameter) which resolves within 15 days. In rare occasions, injection site reactions of more than 9 cm in diameter, or persisting more than 15 days, may be observed.
Vaccinated animals may very commonly have a mild, transitory hyperthermia which returns to normal within 24 hours. In rare occasions hyperthermia can be observed for a longer period of time.
In very rare cases, anaphylactic reactions may be observed after vaccination.

* 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 during pregnancy or lactation.

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 decided on a case by case basis.

4.9 Amounts to be administered and administration route

The vaccine should be shaken well before use.
Administer a 2.0 ml dose by intramuscular injection in the neck. Second vaccination should be administered preferably at the alternate side of the neck.

Vaccination Schedule:
Pigs can be vaccinated from the age of 7 days and older. A second vaccination should be given 14-21 days later.

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

After administration with a double dose, reactions in pigs are similar to those seen after administration of a single dose but injection site reactions may persist for longer (very commonly up to more than 14 days), and may be larger.

4.11 Withdrawal period(s)

Zero days.

5. IMMUNOLOGICAL PROPERTIES

An inactivated liquid vaccine to stimulate active immunity against *Mycoplasma hyopneumoniae* and *Haemophilus parasuis* serotypes 4 and 5.
ATCVet code: QI09AB17

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Thiomersal
Amaranth
Ethylenediaminetetraacetic acid
Sodium chloride
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: 2 years
Shelf life after first opening the immediate packaging: use immediately.

6.4 Special precautions for storage

Store and transport refrigerated at 2°C – 8°C.
Store protected from light in the original container.
Do not freeze.

6.5 Nature and composition of immediate packaging

High density polyethylene vials:

25 ml vial containing 10 doses.
60 ml vial containing 25 doses.
120 ml vial containing 50 doses.
250 ml vial containing 125 doses.
Packaging: Cardboard box with 1 or 10 high density polyethylene vials of 25, 60, 120 or 250 ml with a chlorobutyl rubber stopper and aluminium cap.

Low density polyethylene sachet:

100 ml sachet containing 50 doses.
Packaging: Cardboard box with 1 or 10 low density polyethylene sachets of 100 ml with a bromobutyl rubber stopper and aluminium cap.

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 products should be disposed of in accordance with national requirements.

7. MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER

Vm 42058/4138

9. DATE OF FIRST AUTHORISATION

21 March 2006

10. DATE OF REVISION OF THE TEXT

25 October 2019

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