

## **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  $\geq$  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*.  
ATC vet code: QI09AB13.

### **6. PHARMACEUTICAL PARTICULARS**

#### **6.1 List of excipients**

Thiomersal  
EDTA  
Amaranth  
Sodium chloride  
Sodium phosphate dibasic heptahydrate  
Water for injections

#### **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**

High density polyethylene (HDPE) bottles containing 100 ml (50 doses) or 250 ml (125 doses) of vaccine closed with chlorobutyl rubber stoppers and sealed with aluminium caps.

Pack sizes:

Carton box containing 1 bottle of 50 or 125 doses

Carton box containing 10 bottles of 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 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  
Surrey  
KT22 7LP

## **8. MARKETING AUTHORISATION NUMBER**

Vm 42058/3025

## **9. DATE OF FIRST AUTHORISATION**

15 September 1995

## **10. DATE OF REVISION OF THE TEXT**

November 2023

Approved 24 November 2023

A handwritten signature in black ink, appearing to read "J. Hunter", is written below the approval date.