

# M + PAC

## 1. SUMMARY OF PRODUCT CHARACTERISTICS

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#### 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

M + PAC

#### 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

##### Active substance(s):

Per 1 ml volume:

*Mycoplasma hyopneumoniae* (inactivated):  $\geq 1.47$  RPU\*

##### Adjuvant(s):

0.134 ml Light mineral oil

1 mg Aluminium (as hydroxide)

##### Excipients:

0.10 mg Thiomersal (preservative)

\* Relative Protective Unit as defined against a reference vaccine

#### 3. PHARMACEUTICAL FORM

Emulsion for injection

#### 4. CLINICAL PARTICULARS

##### 4.1 Target species

Pigs

##### 4.2 Indications for use

For the active immunisation of finishing pigs in order to reduce the frequency and severity of lung lesions caused by *Mycoplasma hyopneumoniae*.

Onset of immunity after vaccination with either two doses of 1 ml or a single dose of 2 ml is 21 days after the last vaccination. The duration of immunity for both vaccination schedules is at least 6 months after the last vaccination.

##### 4.3 Contraindications

None

##### 4.4 Special warnings

None

##### 4.5 Special precautions for use

###### Special precautions for use in animals

Vaccinate only healthy animals

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

This product contains mineral oil. Accidental injection / self injection may result in severe pain and swelling, particularly if injected into a joint or finger, and in rare cases in the loss of the affected finger if prompt medical attention is not given.

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If accidental injection occurs with this product, even if only a very small amount has been injected – seek prompt medical advice and take package insert to the physician. If pain persists for more than 12 hours after initial medical examination, seek medical advice again.

To the physician: This product contains mineral oil. Even if small amounts have been injected, accidental injection with this product can cause intense swelling, which may, for example result in ischaemic necrosis and even the loss of a digit. Expert, PROMPT surgical attention is required and may necessitate early incision and irrigation of the injected area, especially where there is involvement of finger pulp or tendon.

#### **4.6 Adverse reactions (frequency and seriousness)**

Minor transient systemic reactions consisting of dizziness, increased respiration rate and temperature increases may occur after vaccination. All animals return to normal within 1 to 2 days. In exceptional cases hypersensitivity reactions may occur. Transient local reactions consisting of a slight swelling are observed. In rare cases a granuloma may be seen at the injection site which resolves over time.

#### **4.7 Use during pregnancy and lactation**

Do not vaccinate 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 from the concurrent use of this vaccine 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 an individual case by case basis.

#### **4.9 Amounts to be administered and administration route**

Vaccinate pigs by the intramuscular route, preferably on alternate sides of the neck.

One dose vaccination schedule:

Vaccinate pigs from an age of 3 weeks with a single dose of 2 ml.

Two dose vaccination schedule:

Vaccinate pigs from 7 days of age with 2 doses of 1 ml with an interval of 14 – 28 days.

The container should be well shaken before withdrawing a dose.

Syringes and needles must be sterile before use. The injection should be performed in an area of clean, dry skin, taking appropriate precautions to avoid contamination.

Follow standard aseptic procedures.

M + PAC is efficacious in the presence of maternally derived antibodies (MDA)

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

No additional undesirable side effects other than those given in Section 4.6 have been observed after the administration of 4 ml of the vaccine.

#### **4.11 Withdrawal period(s)**

Zero days

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### 5. IMMUNOLOGICAL PROPERTIES

The vaccine contains the strain ATCC #25934 of *Mycoplasma hyopneumoniae* inactivated with bromoethylene imine and adjuvanted. The vaccine induces an active immunity against *M. hyopneumoniae* as demonstrated by virulent challenge and is efficacious in the presence of maternally derived antibodies.

### 6. PHARMACEUTICAL PARTICULARS

#### 6.1 Incompatibilities

Do not mix with any other vaccine / immunological product.

#### 6.2 Shelf life

2 years

Shelf life after first opening the container: 8 hours.

#### 6.3 Special precautions for storage

Store and transport refrigerated (+2°C - +8°C)

Do not freeze

Protect from direct sunlight

#### 6.4 Nature and composition of immediate packaging

Cardboard boxes with either 1, 2, 5 or 10 plastic bottles of 50, 100, and 200 ml. The bottles are closed with a rubber stopper sealed with an aluminium cap.

Not all pack sizes may be marketed

#### 6.5 Special precautions for the disposal of unused 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 local requirements.

### 7. MARKETING AUTHORISATION HOLDER

Intervet International BV

Wim de Körverstraat 35

5831 AN Boxmeer

The Netherlands

Represented by national companies in the Member States

### 8. MARKETING AUTHORISATION NUMBER(S)

### 9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

### 10. DATE OF REVISION OF THE TEXT

### PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable