1 NAME OF THE VETERINARY MEDICINAL PRODUCT

M+PAC

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active ingredients:	Quantity per 1 ml volume :
Mycoplasma hyopneumoniae, inactivated	≥ 1.47 RPU (*)
Light mineral oil	0.134 ml
Aluminium (as hydroxide)	1.0 mg
Thiomersal	0.10 mg
Excipients	qs 1ml

For full list of excipients, see section 6.1.

(*) Relative Unit defined against a reference vaccine

3 PHARMACEUTICAL FORM

Emulsion for injection.

[White liquid emulsion]

4 CLINICAL PARTICULARS

4.1 Target species

Pig (fattening pigs, from 7 days of age).

4.2 Indications for use, specifying the target species

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

For vaccination with 2 doses of 1 ml given 2-4 weeks apart, protection has been demonstrated 35 days post initial dose and the duration of immunity is at least 6 months. In field studies, only seroconversion has been demonstrated in pigs receiving two 1 ml doses.

For vaccination with 1 dose of 2 ml, protection has been shown 24 days after vaccination and duration of immunity is at least 6 months after vaccination.

4.3 Contraindications

None.

4.4 Special warnings

Piglets vaccinated from 7 days of age :
Under laboratory conditions, piglets from 4 weeks of age after administration of 2 doses of 1 ml at 2-4 weeks interval produced a protective immune response in the presence of passively acquired antibodies. Furthermore, under field conditions piglets from 6 days old produced a serological response in the presence of such antibodies.

Piglets vaccinated from 21 days of age :
Analysis of laboratory tests after the administration of a single 2 ml dose have shown no correlation between antibody level of maternal origin at the time of vaccination and the efficacy of vaccination; this suggests that maternally derived immunity in piglets does not interfere with vaccination.

4.5 Special precautions for use

Special precautions for use in animals:

Not applicable.

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

In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

To the user: 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 case could result in the loss of the affected finger if prompt medical attention is not given. If you are accidentally injected with this product, seek prompt medical advice even if only a very small amount is injected and take the package leaflet with you. If pain persists for more than 12 hours after 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)

A small proportion of pigs may experience polypnea and dizziness within 5-10 minutes of first vaccination. This resolves within 4 hours without treatment or further adverse effect on the animal. An increase in respiration rate may also occur in a small proportion of piglets within a few hours of injection with either a 1 or 2 ml dose. Hyperthermia may occur in a small proportion of piglets given 1 ml (<39.8°C) and a higher proportion given 2 ml (mean 40.2°C), returning to normal within 24-48 hours. Adverse reactions are uncommon after the second vaccination. Local reactions at the injection site are common but are restricted to a slight swelling (<2 cm diameter) which disappears within 24-48 hours of injection. In rare cases a granuloma may occur in the muscle at the injection site which may last over 21 days but resolves over time. Correct aseptic technique will reduce this possibility further. [These observations were made during small scale laboratory studies and field trials].

In rare cases, emesis, dyspnoea, ataxia, muscle tremor, convulsion, diarrhoea, lethargy or anorexia may be observed following vaccination.

In the event of hypersensitivity reactions (shock), appropriate treatment such as adrenaline should be administered without delay.

4.7 Use during pregnancy or lactation

The use is not recommended during pregnancy or lactation.

4.8 Interactions 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. It is therefore recommended that no other vaccines should be administered within 14 days before or after vaccination with this product.

4.9 Amounts to be administered and administration route

Pigs from 7 days of age: 1 dose of 1 ml. This 1 ml dose should be repeated after 14 – 28 days.

Pigs from 21 days of age : 1 single dose of 2 ml or 2 doses of 1 ml administered at an interval of 14-28 days.

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

The vial should be well shaken before withdrawing a dose. There is no need to warm the vaccine before use. Syringes and needles must be sterile before use. The injection should be performed in a clean and dry skin area, taking appropriate precaution to avoid contamination.
Follow usual aseptic procedures.

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

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

4.11 Withdrawal period(s)

Zero days.

5 IMMUNOLOGICAL PROPERTIES

ATC vet code: QI09AB-13
The vaccine contains the strain ATTC#25934 of *Mycoplasma hyopneumoniae* inactivated with bromoethylenimine and adjuvanted. The vaccine induces an active immunity against *M. hyopneumoniae* as demonstrated by virulent challenge.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sorbitan oleate
Polysorbate
Ethyl alcohol
Glycerol
Sodium chloride (0.85% w/v)

6.2 Incompatibilities

Do not mix with any other vaccine or immunological 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: 8 hours.

6.4 Special precautions for storage

Store and transport refrigerated (+2°C to +8°C).
Do not freeze.
Protect from light.

6.5 Nature and composition of immediate packaging

Nature of primary packaging:
High density polyethylene bottle closed with Teflon coated bromobutylrubber stoppers or PET bottles closed with nitrile rubber stoppers
Rubber stopper: type I
Aluminium seal

Presentations for sale:
Box of 1 bottle of 50 ml
Box of 2 bottles of 50 ml
Box of 5 bottles of 50 ml
Box of 10 bottles of 50 ml
Box of 1 bottle of 100 ml
Box of 2 bottles of 100 ml
Box of 5 bottles of 100 ml
Box of 10 bottles of 100 ml
Box of 1 bottle of 200 ml
Box of 2 bottles of 200 ml
Box of 5 bottles of 200 ml
Box of 10 bottles of 200 ml

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

7 MARKETING AUTHORISATION HOLDER

Intervet Ireland Limited

8 MARKETING AUTHORISATION NUMBER(S)

VPA10996/236/001

9 DATE OF FIRST AUTHORISATION / RENEWAL OF THE AUTHORISATION

12/09/2002

10 DATE OF REVISION OF THE TEXT

15/02/2024

PROHIBITION OF SALE, SUPPLY AND/OR USE:

Not applicable.