1. NAME OF THE VETERINARY MEDICINAL PRODUCT

MYPRAVAC SUIS suspension for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Composition per dose (2 ml):

Active substance:
Mycoplasma hyopneumoniae, strain J, Inactivated ≥ 1.0 guinea pig-ED_{80}

1 ED_{80}: 1/4 dose of vaccine administered twice with an interval of 15 days induces seroconversion (*M. hyopneumoniae* specific antibodies) in (at least) 80 percent of the laboratory animals.

Adjuvants:

Levamisole (as hydrochloride)	1.8 mg
Carbomer	10 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Methyl parahydroxybenzoate	2.4 mg
Sodium hydroxide	
Sodium chloride	
Sodium bisulphite	
Water for injections	

Pinkish homogeneous suspension.

3. CLINICAL INFORMATION

3.1 Target species

Pigs (for fattening).

3.2 Indications for use for each target species

For active immunisation of healthy susceptible piglets between 7 and 10 days of age to reduce lung lesion scores and weight loss associated with *Mycoplasma hyopneumoniae* infection.

Duration of immunity of 70 days after the first vaccination has been shown by experimental infection. Onset and longer duration of immunity have not been investigated in laboratory trials. But, under field conditions, improved weight gain and feed conversion rate over the growth period (6 months) have been demonstrated.

3.3 Contraindications

Do not use in helminth infested pigs due to risk of selection for levamisole and benzimidazole resistant helminths.

3.4 Special warnings

Vaccinate healthy animals only.
The development of immunity may be slower in animals with passive immunity.

3.5 Special precautions for use

Special precautions for safe use in the target species:

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 leaflet or the label to the physician.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Pigs (for fattening):

Very common (>1 animal / 10 animals treated):	Elevated temperature[1] Injection site lesion[2]
Uncommon (1 to 10 animals / 1,000 animals treated):	Trembling
Rare (1 to 10 animals / 10,000 animals treated):	Vomiting
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Apathy Hypersensitivity reaction[3]

[1]A rise in temperature up to 1ºC 1-2 days can be seen.
[2]Long lasting microscopic lesions (multifocal to diffuse granulomatous myositis with presence of granular, eosinophilic material) may be detected.
[3]In the event of an anaphylactic reaction appropriate treatment such as adrenaline should be administered without delay.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:
Do not use during pregnancy and lactation.

Fertility:
Do not use in breeding animals.

3.8 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.

3.9 Administration routes and dosage

Intramuscular use.

It is recommended that the vaccine should be allowed to warm to a temperature of between 15ºC and 25ºC before administration.
Shake before use.

Recommended vaccination scheme:
Administer one dose of 2 ml per pig, at 7 to 10 days of age. This 2 ml dose should be repeated after 21 days. Vaccinate pigs by deep intramuscular injection into the neck muscles at the cervical-lateral area behind the ear. It is recommended that the second dose should be given preferably on alternate sides.

Pigs should not be revaccinated after completion of the recommended primary regime.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

No effects other than those indicated under section 3.6 have been observed following administration of twice the recommended dose. The rise in rectal temperature and microscopic lesions at the injection site are more severe than after administration of a single dose.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable

3.12 Withdrawal periods

Meat: 2 days.

4. IMMUNOLOGICAL INFORMATION

4.1 ATCvet code: QI09AB13.

The vaccine contains the strain J of *Mycoplasma hyopneumoniae* inactivated with bromoethylenimine and adjuvanted with levamisole and carbomer. The vaccine induces an active immunity in fattening pigs vaccinated at 7 days old against *M. hyopneumoniae* as demonstrated by virulent challenge.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product.

5.2 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale (glass bottles): 2 years.

Shelf-life of the veterinary medicinal product as packaged for sale (HDPE bottles): 9 months.
Shelf-life after first opening the immediate packaging: Use immediately.

5.3 Special precautions for storage

Store and transport refrigerated (2ºC - 8ºC).
Do not freeze.

5.4 Nature and composition of immediate packaging

The container consists of 20 ml (10 doses) Type I coloured glass vials (Ph. Eur.) 100 ml (50 doses) Type II coloured glass vials (Ph. Eur.) 250 ml (125 doses) and 500 ml (250 doses) high density polyethylene plastic bottles (Ph. Eur.), Type II rubber stoppers (Ph. Eur.) and aluminium caps.

Package sizes:

- Cardboard box with one glass vial of 10 doses.
- Cardboard box with one glass vial of 50 doses.
- Cardboard box with 10 glass vials of 10.
- Cardboard box with 12 plastic bottles of 125 doses.
- Cardboard box with 12 plastic bottles of 250 doses.

Not all pack sizes may be marketed.

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

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

LABORATORIOS HIPRA, S.A.

7. MARKETING AUTHORISATION NUMBER(S)

VPA10846/004/001

8. DATE OF FIRST AUTHORISATION

02 May 2003

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

23 September 2024

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product not subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).