B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

MYPRAVAC SUIS suspension for injection

2. 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:
Methyl parahydroxybenzoate 2.4 mg

Pinkish homogeneous suspension.

3. Target species

Pigs (for fattening).

4. Indications for use

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.

5. Contraindications

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

6. Special warnings

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

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.

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

Fertility:
Do not use in breeding animals.

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.

Overdose:
No effects other than those indicated under section "adverse events" 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.

Major incompatibilities:
Do not mix with any other veterinary medicinal product.

7. 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 product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system: {national system details}

8. Dosage for each species, routes and method of administration

Intramuscular 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.

9. Advice on correct administration

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

Shake before use.

10. Withdrawal periods

Meat: 2 days.

11. Special storage precautions

Keep out of the sight and reach of children.
Store and transport refrigerated (2ºC - 8ºC).

Do not freeze.

Shelf-life after first opening the immediate packaging: Use immediately.

Do not use this veterinary medicinal product after the expiry date which is stated on the label or carton. The expiry date refers to the last day of that month.

12. Special precautions for disposal

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 applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription..

14. Marketing authorisation numbers and pack sizes

Marketing authorisation number:

Pack 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 doses.

- 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.

15. Date on which the package leaflet was last revised

{DD/MM/YYYY}

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

16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release and contact details to report suspected adverse reactions:

LABORATORIOS HIPRA, S.A.
Avda. la Selva, 135
17170 AMER (Girona) SPAIN
TEL: +34 972 43 06 60

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

Local representatives and contact details to report suspected adverse reactions: