ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box of 1x10 ds / 10x10 ds / 1x50 ds / 12x125 ds / 12x250 ds

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

MYPRAVAC SUIS suspension for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Composition per dose (2 ml):
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.

3. PACKAGE SIZE

Vial of 10 doses
10 vials of 10 doses
Vial of 50 doses
12 bottles of 125 doses
12 bottles of 250 doses

4. TARGET SPECIES

Pigs (for fattening).

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Intramuscular use.

7. WITHDRAWAL PERIODS

Withdrawal period: Meat: 2 days.

8. EXPIRY DATE

Exp. {mm/yyyy}
Once opened use immediately.

9. SPECIAL STORAGE PRECAUTIONS

Store and transport refrigerated.
Do not freeze.

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

LABORATORIOS HIPRA S.A.

14. MARKETING AUTHORISATION NUMBERS

Vm 17533/3004

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

LABEL 50 doses / 125 doses / 250 doses

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

MYPRAVAC SUIS suspension for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Composition per dose (2 ml):
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

3. TARGET SPECIES

Pigs (for fattening).

4. ROUTES OF ADMINISTRATION

Intramuscular use.

Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal period: Meat: 2 days.

6. EXPIRY DATE

Exp. {mm/yyyy}.
Once opened use immediately.

7. SPECIAL STORAGE PRECAUTIONS

Store and transport refrigerated.
Do not freeze.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

LABORATORIOS HIPRA, S.A.

9. BATCH NUMBER

Lot {number}

10. PACKAGE SIZE

50 doses
125 doses
250 doses

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

LABEL 10 doses

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

MYPRAVAC SUIS

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Composition per dose (2 ml):
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

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}
Once opened use immediately.

5. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

10 doses

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:
Vm 17533/3004

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. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

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:

Gavin Hall

Approved: 21 January 2025