PACKAGE LEAFLET

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

LABORATORIOS HIPRA, S.A.
Avda. La Selva, 135
17170 - AMER (Girona) Spain

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

MYPRAVAC SUIS,
Pinkish homogeneous suspension for injection for pigs.

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

Composition per dose (2ml):
Inactivated *Mycoplasma hyopneumoniae* strain J ≥1.0 guinea pig-ED_{80}; Levamisole (as hydrochloride) 1.8 mg; Carbomer 10 mg; Methyl parahydroxybenzoate 2.4 mg.

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.

4. INDICATIONS

Fattening pigs: 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 unhealthy animals.

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

Do not use in breeding animals and in pregnant and lactating sows.

6. ADVERSE REACTIONS

A slight transient rise in temperature up to 1ºC 1-2 days after each vaccination can be seen.

After vaccination, vomiting, trembling and apathy have occasionally been observed.

Hypersensitivity reactions may occur. In the event of an anaphylactic reaction appropriate treatment such as adrenaline should be administered without delay.

Long lasting microscopic lesions at the injection site (multifocal to diffuse granulomatous myositis with presence of granular, eosinophilic material) may be detected after vaccination.

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Species: Pigs (fattening pigs)
Age: from 7 days of age onwards.

8. DOSAGE FOR EACH SPECIES, ROUTES AND METHOD OF ADMINISTRATION

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 PERIOD

Meat: 2 days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight of children.

Store and transport at 2ºC - 8ºC. Do not freeze.

Shelf-life after first opening the container: Use immediately after first opening.

Do not use after the expiry date stated on the label or carton.

12. SPECIAL WARNINGS

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

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

Do not mix with any other vaccine or immunological product.

No information is available on the compatibility of this vaccine with any other. Therefore the safety and efficacy of this product when used with any other (either when used on the same day or different times) has not been demonstrated.

No effects other than those indicated under section “adverse reactions” 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.

IE only: Prior to first use on a farm, it is strongly recommended that the advice of a veterinary practitioner is sought.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

March 2008.

15. OTHER INFORMATION

IE only:
LM: Licensed Merchant
VPA No. 10846/4/1

UK only:
POM (V): To be supplied only on Veterinary Prescription
Vm 17533/4001

For animal treatment only.

Presentations:

- Box of 1 vial of 10 doses.
- Box with 1 vial of 50 doses.
- Box of 10 vials of 10 doses.
- Box with 12 bottles of 125 doses.
- Box with 12 bottles of 250 doses.

Not all pack sizes may be marketed.

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

BOX 1x10 ds / 10x10 ds / 1x50 ds
LABEL FROM THE BOX 12x125 ds / 12x250 ds

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

MYPRAVAC SUIS Suspension for injection for pigs.

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Composition per dose (2 ml):
Inactivated *Mycoplasma hyopneumoniae* strain J ≥1.0 guinea pig-ED_{80}; Levamisole (as hydrochloride) 1.8 mg; Carbomer 10 mg; Methyl parahydroxybenzoate 2.4 mg.

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 (fattening pigs).

5. INDICATIONS

Fattening pigs: 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.

6. METHOD AND ROUTE OF ADMINISTRATION

Posology: Administer 2 ml/ pig at 7 to 10 days of age. Repeat after 21 days.
Route of administration: Intramuscular.

7. WITHDRAWAL PERIOD

Withdrawal period: Meat: 2 days.

8. SPECIAL WARNINGS, IF NECESSARY

Read the package leaflet before use.

9. EXPIRY DATE

EXP {month/year}.
Use immediately after first opening.

10. SPECIAL STORAGE CONDITIONS

Store and transport at 2ºC - 8ºC. Do not freeze.

11. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

12. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only.

~~IE only:~~
LM: Licensed Merchant
VPA No. 10846/4/1

UK only:
POM (V): To be supplied only on Veterinary Prescription
Vm 17533/4001

13. THE WORDS "KEEP OUT OF THE REACH AND SIGHT OF CHILDREN"

Keep out of the reach and sight of children.

14. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

LABORATORIOS HIPRA, S.A.
Avda. La Selva, 135
17170 - AMER (Girona) Spain

15. MANUFACTURER'S BATCH NUMBER

Batch{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 for pigs.

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Composition per dose (2 ml):
Inactivated *Mycoplasma hyopneumoniae* strain J ≥1.0 guinea pig-ED_{80}; Levamisole (as hydrochloride) 1.8 mg; Carbomer 10 mg; Methyl parahydroxybenzoate 2.4 mg.

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

50 doses
125 doses
250 doses

4. TARGET SPECIES

Pigs (fattening pigs).

5. INDICATIONS

Fattening pigs: 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.

6. METHOD AND ROUTE OF ADMINISTRATION

Posology: Administer 2 ml/ pig at 7 to 10 days of age. Repeat after 21 days.
Route of administration: Intramuscular.

7. WITHDRAWAL PERIOD

Withdrawal period: Meat: 2 days.

8. SPECIAL WARNINGS, IF NECESSARY

Read the package leaflet before use.

9. EXPIRY DATE

EXP {month/year}.
Use immediately after first opening.

10. SPECIAL STORAGE CONDITIONS

Store and transport at 2ºC - 8ºC. Do not freeze.

11. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

12. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only.

13. THE WORDS "KEEP OUT OF THE REACH AND SIGHT OF CHILDREN"

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VPA No. 10846/4/1

UK only:
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Vm 17533/4001

Keep out of the reach and sight of children.

14. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

LABORATORIOS HIPRA, S.A.
Avda. La Selva, 135
17170 - AMER (Girona) Spain

15. MANUFACTURER'S BATCH NUMBER

Batch{number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

LABEL 10 doses

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

MYPRAVAC SUIS Suspension for injection for pigs.

2. QUANTITY OF THE ACTIVE SUBSTANCE

Composition per dose (2 ml):
Inactivated *Mycoplasma hyopneumoniae* strain J ≥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. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

10 doses

4. ROUTE OF ADMINISTRATION

Intramuscular

5. WITHDRAWAL PERIOD

Withdrawal period: Meat: 2 days.

6. BATCH NUMBER

Batch {number}

7. EXPIRY DATE

EXP {month/year}
Use immediately after first opening.

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

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