SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

MYPRAVAC SUIS
Suspension for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Composition per dose (2 ml):

Active substance:
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

Adjuvants:
Levamisole (as hydrochloride) ..... 1.8 mg
Carbomer ..... 10 mg

Excipients:
Preservative:
Methyl parahydroxybenzoate ..... 2.4 mg

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Suspension for injection.
Pinkish homogeneous suspension.

4. CLINICAL PARTICULARS

4.1 Target species

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

4.2 Indications for use, specifying the target species

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.

4.3 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.

See section 4.7.

4.4 Special warnings for each target species

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

4.5 Special precautions for use

Special precautions for use in animals

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.

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.

4.6 Adverse reactions (frequency and seriousness)

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.

4.7 Use during pregnancy, lactation or lay

Pregnancy: do not use during pregnancy.
Lactation: do not use during lactation.
Fertility: do not use in breeding animals.

4.8 Interaction with other medicinal products and other forms of interaction

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."

4.9 Amounts to be administered and administration route

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.

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

No effects other than those indicated under section 4.6 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.

4.11 Withdrawal period

Meat: 2 days.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Inactivated Mycoplasma vaccine, 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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Levamisole hydrochloride, Carbomer, Sodium hydroxide, Methyl parahydroxybenzoate, Sodium chloride, Sodium bisulphite, Water for injections.

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 (glass bottles): 24 months.
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 after first opening.

6.4. Special precautions for storage

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

6.5 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 with a rubber stopper and aluminium cap.
- Cardboard box with one glass vial of 50 doses with a rubber stopper and aluminium cap.
- Cardboard box with 10 glass vials of 10 doses with a rubber stopper and aluminium cap.
- Cardboard box with 12 plastic bottles of 125 doses with a rubber stopper and aluminium cap.
- Cardboard box with 12 plastic bottles of 250 doses with a rubber stopper and aluminium cap.

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

7. MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER

UK only: Vm 17533/4001
IE only: 10846/4/1

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first Authorisation: 7th February 2002 (United Kingdom).
Common Renewal Date: 20th March 2008.

10 DATE OF REVISION OF THE TEXT

March 2008

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable