

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-ED₈₀

1 ED₈₀: 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

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-ED₈₀

1 ED₈₀: 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-ED₈₀

1 ED₈₀: 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