MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

{10 and 250 doses LABELS}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

SUISENG Suspension for injection for pigs.

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Each dose (2 ml) :
F4ab, F4ac, F5 and F6 fimbrial adhesins of *E. coli*; LT enterotoxoid of *E. coli,* Toxoid of *Clostridium perfringens* type C, Toxoid *Clostridium novyi* type B.

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

10 doses
25 doses

4. ROUTE(S) OF ADMINISTRATION

Intramuscular use.

5. WITHDRAWAL PERIOD

Withdrawal period: Zero days.

6. BATCH NUMBER

Batch {number}

7. EXPIRY DATE

EXP {month/year}
Once broached use within 8-10 hours.

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.
UK only: Vm: 17533/4009. POM-V
IE only: VPA. 10846/010/001
LM

Local Representative:
HIPRA UK AND IRELAND, Ltd.
Innovation Center, Office 503
BioCity Nottingham
Pennyfoot Street
Nottingham
NG1 1GF - UNITED KINGDOM
e-mail: ukandireland@hipra.com

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

{50 and 125 doses LABELS}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

SUISENG Suspension for injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each dose (2 ml) :

F4ab fimbrial adhesin of *E. coli*	≥65% ER_{60}
F4ac fimbrial adhesin of *E. coli*	≥78% ER_{70}
F5 fimbrial adhesin of *E. coli*	≥79% ER_{50}
F6 fimbrial adhesin of *E. coli*	≥80% ER_{25}
LT Enterotoxoid of *E. coli*	≥55% ER_{70}
Toxoid *Clostridium perfringens*, type C	≥35% ER_{25}
Toxoid *Clostridium novyi*, type B	≥50% ER_{120}

3. PHARMACEUTICAL FORM

Suspension for injection.

4. PACKAGE SIZE

50 doses,
125 doses

5. TARGET SPECIES

Pigs (sows and gilts).

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Intramuscular use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Withdrawal period: Zero days.

9. SPECIAL WARNING(S), IF NECESSARY

Accidental self-injection is dangerous.

10. EXPIRY DATE

EXP {month/year}
Once broached use within 8-10 hours.

11. SPECIAL STORAGE CONDITIONS

Store and transport refrigerated (2 ºC and 8 ºC). Protect from light. Do not freeze.

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

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only. To be supplied only on veterinary prescription.

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

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

LABORATORIOS HIPRA, S.A.
Avda. la Selva, 135
17170- AMER (Girona) SPAIN

Local Representative:
HIPRA UK AND IRELAND, Ltd.
Innovation Center, Office 503
BioCity Nottingham
Pennyfoot Street
Nottingham
NG1 1GF - UNITED KINGDOM
e-mail: ukandireland@hipra.com

16. MARKETING AUTHORISATION NUMBER(S)

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IE only: VPA. 10846/010/001
LM

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARDBOARD BOXES

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

SUISENG Suspension for injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each dose (2 ml) :

F4ab fimbrial adhesin of *E. coli*	≥65% ER_{60}
F4ac fimbrial adhesin of *E. coli*	≥78% ER_{70}
F5 fimbrial adhesin of *E. coli*	≥79% ER_{50}
F6 fimbrial adhesin of *E. coli*	≥80% ER_{25}
LT Enterotoxoid of *E. coli*	≥55% ER_{70}
Toxoid *Clostridium perfringens*, type C	≥35% ER_{25}
Toxoid *Clostridium novyi*, type B	≥50% ER_{120}

3. PHARMACEUTICAL FORM

Suspension for injection.

4. PACKAGE SIZE

10 doses,
25 doses,
50 doses,
125 doses.

5. TARGET SPECIES

Pigs (sows and gilts).

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Intramuscular use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Withdrawal period: Zero days.

9. SPECIAL WARNING(S), IF NECESSARY

Accidental self-injection is dangerous.

10. EXPIRY DATE

EXP {month/year}
Once broached use within 8-10 hours.

11. SPECIAL STORAGE CONDITIONS

Store and transport refrigerated (2 ºC and 8 ºC). Protect from light. Do not freeze.

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

Disposal: read package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only. To be supplied only on veterinary prescription.

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

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

LABORATORIOS HIPRA, S.A.
Avda. la Selva, 135
17170- AMER (Girona) SPAIN

Local Representative:
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e-mail: ukandireland@hipra.com

16. MARKETING AUTHORISATION NUMBER(S)

UK only: Vm: 17533/4009. POM-V
IE only: VPA. 10846/010/001
LM

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

PACKAGE LEAFLET FOR:
SUISENG. Suspension for injection for pigs.

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

Marketing authorisation holder and manufacturer responsible for batch release:
LABORATORIOS HIPRA, S.A.
Avda. la Selva, 135
17170- AMER (Girona) SPAIN
Tel. +34 972 430660
Fax. +34 972 430661
E-mail: hipra@hipra.com

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

SUISENG Suspension for injection for pigs.

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Each dose (2 ml) :

F4ab fimbrial adhesin of *E. coli*	≥65% ER_{60} *
F4ac fimbrial adhesin of *E. coli*	≥78% ER_{70}
F5 fimbrial adhesin of *E. coli*	≥79% ER_{50}
F6 fimbrial adhesin of *E. coli*	≥80% ER_{25}
LT Enterotoxoid of *E. coli*	≥55% ER_{70}
Toxoid *Clostridium perfringens*, type C	≥35% ER_{25}
Toxoid *Clostridium novyi*, type B	≥50% ER_{120}

*% ERx: Percentage of immunized rabbits with a x serological EIA response
Aluminium hydroxide gel
Ginseng extract (equivalent to ginsenosides)
Benzyl alcohol (E1519)

White-yellowish suspension.

4. INDICATION(S)

Piglets: For the passive protection of neonatal piglets by means of the active immunisation of breeding sows and gilts to reduce mortality and clinical signs of neonatal enterotoxicosis, such as diarrhoea caused by enterotoxigenic *Escherichia coli*, which express F4ab (K88ab), F4ac (K88ac), F5 (K99) or F6 (987P) adhesins.
The persistence of these antibodies has not been established.
For the passive immunisation of neonatal piglets against Necrotic Enteritis by means of the active immunisation of breeding sows and gilts to induce seroneutralizing antibodies against the β-toxin of *Clostridium perfringens* type C .
The persistance of antibodies has not been established

Sows and gilts: For active immunisation of breeding sows and gilts to induce seroneutralizing antibodies against α-toxin of *Clostridium novyi* type B. The relevance of the seroneutralizing antibodies was not experimentally determined.
Antibodies have been detected 3 weeks after vaccinaton. The persistence of these antibodies has not been established.

5. CONTRAINDICATIONS

None.

6. ADVERSE REACTIONS

Very rare adverse reactions:
- A small granuloma may occur in the muscle tissue at the injection site. The administration of the vaccine can cause the appearance of a small (less than 3 cm), local, transitory swelling (for 24-48 hours). In a few cases, temporary small nodules can be observed, which disappear within 2-3 weeks.

- The vaccination may cause a slight increase in body temperature for a transient period after vaccination (4-6 hours after injection).Unusually, an increase in rectal temperature higher than 1.5ºC, lasting less than 6 hours, may occur.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals displaying adverse reactions during the course of one treatment)

- common (more than 1 but less than 10 animals in 100 animals)

- uncommon (more than 1 but less than 10 animals in 1,000 animals)

- rare (more than 1 but less than 10 animals in 10,000 animals)

- very rare (less than 1 animal in 10,000 animals, including isolated reports)

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

7. TARGET SPECIES

Pigs (sows and gilts).

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Intramuscular, into the neck muscles.
Pigs: 2 ml/animal.

The basic vaccination scheme consists of two doses: the first dose at approximately 6 weeks before farrowing and a second dose at approximately 3 weeks before farrowing .
It is recommended that the second dose should be given preferably on alternate sides

Revaccination: On each subsequent gestation, administer one dose 3 weeks before the expected date of farrowing.

9. ADVICE ON CORRECT ADMINISTRATION

It is advisable to administer the vaccine at a temperature between +15ºC and +25ºC.
Shake before use.
In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

10. WITHDRAWAL PERIOD

Zero days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Store and transport refrigerated (2 ºC and 8 ºC). Protect from light. Do not freeze.
Do not use after the expiry date stated on the label.
Shelf-life after first opening the container: 8-10 hours.

12. SPECIAL WARNING(S)

Special precautions for use in animals:
Only healthy animals should be vaccinated.
Hypersensitivity reactions may occur in sensitive animals. In the event of an anaphylactic reaction appropriate treatment such as adrenaline should be administered without delay.

Use during pregnancy, lactation or lay:
Can be used during pregnancy from 6 weeks before the expected farrowing date.

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 (symptoms, emergency procedures, antidotes), if necessary:
No effects other than those indicated under section "Adverse reactions" have been observed following administration of a double dose.

Incompatibilities:
Do not mix with any other veterinary medicinal product.

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 product should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

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15. OTHER INFORMATION

Pack sizes:

- Cardboard box with 1 glass or PET vial of 10 doses (20 ml).
- Cardboard box with 1 glass or PET vial of 25 doses (50 ml).
- Cardboard box with 1 glass or PET vial of 50 doses (100 ml).
- Cardboard box with 1 PET vial of 125 doses (250 ml).

Not all pack sizes may be marketed.

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

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TO BE SUPPLIED ONLY ON VETERINARY PRESCRIPTION

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