SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

SUISENG Suspension for injection for pigs.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose (2 ml):

Active substances:

F4ab fimbrial adhesin of E. coli	≥65% ER60 *
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

Adjuvants:

Aluminium hydroxide gel	0.5 g
Ginseng extract (equivalent to ginsenosides)	4 mg (0.8 mg)

Excipient:

Benzyl alcohol (E1519)	30 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Suspension for injection.
White-yellowish suspension.

4. CLINICAL PARTICULARS

4.1 Target species

Pigs (sows and gilts).

4.2 Indications for use, specifying the target species

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.

4.3 Contraindications

None.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

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.

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)

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)

4.7 Use during pregnancy, lactation or lay

Can be used during pregnancy from 6 weeks before the expected farrowing date.

4.8 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.

4.9 Amounts to be administered and administration route

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.

It is advisable to administer the vaccine at a temperature between +15ºC and +25ºC.
Shake before use.

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 a double dose.

4.11 Withdrawal period(s)

Zero days.

5. IMMUNOLOGICAL PROPERTIES

Stimulates development of protective adhesin-specific *Escherichia coli* antibodies and seroneutralizing antibodies against the heat labile (LT) enterotoxin of *Escherichia coli, Clostridium perfringens* type C and *Clostridium novyi* type B.

Pharmacotherapeutic group: Inactivated bacterial vaccine: Escherichia coli+Clostridial vaccine.
ATCvet code: QI09AB08.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Aluminium hydroxide gel
Ginseng
Benzyl alcohol
Simethicone
PBS solution

6.2 Incompatibilities

Do not mix with any other veterinary medicinal product.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 18 months.
Shelf life after first opening the immediate packaging: 8-10 hours.

6.4. Special precautions for storage

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

6.5 Nature and composition of immediate packaging

20 ml, 50 ml and 100 ml Type-I colourless glass vials, closed with type I rubber stoppers and aluminium caps.
20 ml, 50 ml, 100 ml and 250 ml PET plastic vials, closed with type I rubber stoppers and aluminium caps.

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.

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 product 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

Vm 17533/4009

9. DATE OF FIRST AUTHORISATION

05 November 2015

10. DATE OF REVISION OF THE TEXT

February 2015

PROHIBITION OF SALE, SUPPLY AND/OR USE
Not applicable.

Approved: 09 November 2015