SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Suiseng Coli/C suspension for injection for pigs.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose (2 ml) contains:

Active substances:

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	RP > 1.05**
Toxoid *Clostridium novyi* type B	RP > 1.23

*% ERx: Percentage of immunized rabbits with a X serological EIA response
**RP: Relative potency determined by ELISA.

Adjuvants:

Aluminium hydroxide gel	0.5 g (5.3 mg Al)
Ginseng extract (equivalent to ginsenosides)	4 mg (0.8 mg)

Excipient:

Qualitative composition of excipients and other constituents
Simethicone
Disodium phosphate dodecahydrate
Potassium chloride
Potassium dihydrogen phosphate
Sodium chloride
Water for injections

White-yellowish suspension.

3. CLINICAL INFORMATION

3.1 Target species

Pigs (sows and gilts).

3.2 Indications for use for each 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 seroneutralising antibodies against the β-toxin of *Clostridium perfringens* type C.
The persistence of antibodies has not been established.

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

3.3 Contraindications

None.

3.4 Special warnings

Vaccinate healthy animals only.

3.5 Special precautions for use

Special precautions for safe use in the target species:
Not applicable.

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.

Special precautions for the protection of the environment:
Not applicable.

3.6 Adverse events

Pigs (sows and gilts).

Common (1 to 10 animals / 100 animals treated):	Elevated temperature.[1] Injection site reaction. [2]
Uncommon (1 to 10 animals / 1,000 animals treated):	Injection site nodules.[3]
Very rare (<1 animal / 10,000 animals	Injection site granuloma.

treated, including isolated reports):	
Undetermined frequency (cannot be estimated from the available data)	Hypersensitivity reactions.[4]

[1] Temperature increase observed at 6 hours post-vaccination (mean 0.4ºC, in individual pigs up to 1.2 ºC, uncommonly up to 2ºC) subsiding without treatment within 24 hours post-vaccination.
[2] Palpable inflammatory local reaction (swelling, not more than 2 cm^2) which resolves without treatment within 5 days post-vaccination.
[3] Resolve within 2-3 weeks post-vaccination.
[4] Reactions can be life-threatening in sensitive animals. If such a reaction occurs, appropriate treatment should be administered without delay.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

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

3.8 Interaction with other medicinal products and other forms of interaction

Safety and efficacy data are available which demonstrate that this vaccine can be mixed and administered at one injection site with Suiseng Diff/A. Following administration of the mixed vaccines, an increase in body temperature (mean 1.43 °C, not exceeding 1.87 °C in individual pigs) during the first 6 hours after vaccination occurs very commonly. Injection site swelling (maximum 4 cm) occurs very commonly, but typically will resolve within 4 days.

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.

3.9 Administration routes and dosage

Intramuscular use.
Dose: 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 of the neck.
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.

To ensure the correct mixing with Suiseng Diff/A, the same volumes of Suiseng Diff/A and Suiseng Coli/C should be used. All the contents of Suiseng Coli/C should be transferred into a headspace bottle of Suiseng Diff/A (50 ml bottle with 10 doses, 100 ml bottle with 25 doses and 250 ml bottle with 50 doses).

A pre-sterilised transfer needle can be used according to the following instructions:
- Peel the cap of the bottle containing the vaccine Suiseng Coli/C.
- Connect one end of the transfer needle to the bottle of Suiseng Coli/C.
- Peel the cap of the headspace bottle containing the vaccine Suiseng Diff/A.
- Connect the opposite end of the transfer needle to the bottle of Suiseng Diff/A.
- Transfer all the contents of Suiseng Coli/C into the bottle of Suiseng Diff/A.
- Once finished, separate both bottles and discard the needle transfer.

Shake well before use. Administer one single dose of 4 ml of the mixed vaccines.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

None known.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Meat and offal: Zero days.

4. IMMUNOLOGICAL INFORMATION

4.1 ATCvet code: QI09AB08.

Inactivated bacterial vaccine: Escherichia coli+Clostridial vaccine.

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

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product, except with Suiseng Diff/A.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 18 months.
Shelf life after first opening the immediate packaging: 10 hours.
Shelf life after mixing with Suiseng Diff/A: 10 hours.

5.3 Special precautions for storage

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

5.4 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.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

LABORATORIOS HIPRA, S.A.

7. MARKETING AUTHORISATION NUMBER

Vm 17533/3000

8. DATE OF FIRST AUTHORISATION

01 May 2020

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

October 2023

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

Approved 15 February 2024