ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARDBOARD BOXES

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Suiseng Coli/C suspension for injection.

2. STATEMENT OF ACTIVE SUBSTANCES

Each dose (2 ml) contains :

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

3. PACKAGE SIZE

10 doses (20 ml),
25 doses (50 ml),
50 doses (100 ml),
125 doses (250 ml).

4. TARGET SPECIES

Pigs (sows and gilts).

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Intramuscular use.

7. WITHDRAWAL PERIODS

Withdrawal period: Zero days.

8. EXPIRY DATE

Exp. {mm/yyyy}
Once broached use within 10 hours.

9. SPECIAL STORAGE PRECAUTIONS

Store and transport refrigerated. Protect from light. 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

Vm 17533/3000

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

{50 and 125 doses LABELS}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Suiseng Coli/C suspension for injection.

2. STATEMENT OF ACTIVE SUBSTANCES

Each dose (2 ml) contains:

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

3. TARGET SPECIES

Pigs (sows and gilts).

4. ROUTES OF ADMINISTRATION

Intramuscular use.
Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal period: Zero days.

6. EXPIRY DATE

Exp. {mm/yyyy}
Once broached use within 10 hours.

7. SPECIAL STORAGE PRECAUTIONS

Store and transport refrigerated. Protect from light. Do not freeze.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

LABORATORIOS HIPRA, S.A.

9. BATCH NUMBER

Lot {number}

10. PACKAGE SIZE

50 doses (100 ml).
125 doses (250 ml).

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

{10 and 25 doses LABELS}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Suiseng Coli/C.

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Each dose (2 ml) contains :
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. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}
Once broached use within 10 hours.

5. PACKAGE SIZE

10 doses (20 ml).
25 doses (50 ml).

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Suiseng Coli/C suspension for injection for pigs.

2. Composition

Each dose (2 ml) contains :

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.

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

White-yellowish suspension.

3. Target species

Pigs (sows and gilts).

4. Indications for use

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.

5. Contraindications

None.

6. Special warnings

Special warnings:
Vaccinate healthy animals only.

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.

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

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.

Overdose:
None known.

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

7. 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 treated, including isolated reports):	Injection site granuloma.

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 product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details on this leaflet, or via your national reporting system: {national system details}.

8. Dosage for each species, routes and method of administration

Intramuscular use.
Dose: 2 ml/animal.

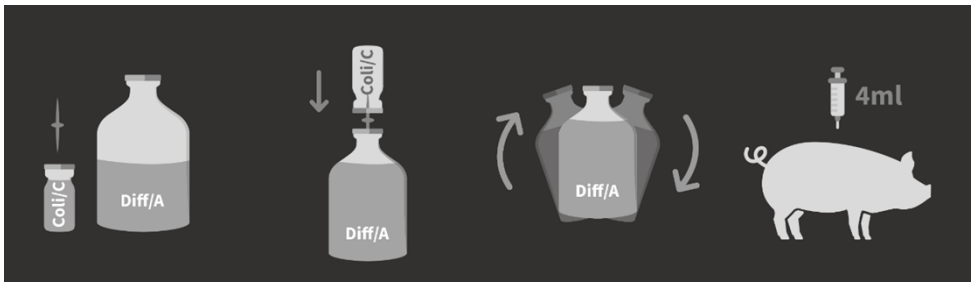
The basic vaccination scheme consists of two doses: the first dose at approximately 6 weeks before farrowing and a second dose at approximately 3 weeks before farrowing .
It is recommended that the second dose should be given preferably on alternate sides of the neck.

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

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.



9. Advice on correct administration

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

10. Withdrawal periods

Zero days.

11. Special storage precautions

Keep out of the sight and reach of children.
Store and transport refrigerated (2 ºC-8 ºC). Protect from light. Do not freeze.
Do not use this veterinary medicinal product after the expiry date, which is stated on the label after Exp. The expiry date refers to the last day of that month.
Shelf-life after first opening the immediate packaging: 10 hours.
Shelf life after mixing with Suiseng Diff/A: 10 hours.

12. Special precautions for disposal

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 applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Marketing authorisation number:

Vm 17533/3000

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.

15. Date on which the package leaflet was last revised

October 2023

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

16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release and contact details to report suspected adverse reactions:

LABORATORIOS HIPRA, S.A.
Avda. La Selva 135
17170 Amer (Girona) SPAIN
Tel. +34 972 43 06 60

Local representatives and contact details to report suspected adverse reactions:

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

17. Other information

Approved 15 February 2024