ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Suiseng Diff/A suspension for injection for pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose (2 ml) contains:

Active substances:

Clostridioides difficile, toxoid A (TcdA)	≥ 1.60 RP*
Clostridioides difficile, toxoid B (TcdB)	≥ 1.65 RP*
Clostridium perfringens type A, α-toxoid	≥ 1.34 RP*

* RP: Relative Potency determined by ELISA

Adjuvants:

Aluminium hydroxide gel	0.6 g
Ginseng extract (equivalent to ginsenosides)	
DEAE-dextran	

Excipientss:

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

Yellowish-white suspension.

3. CLINICAL INFORMATION

3.1 Target species

Pigs (pregnant sows and gilts).

3.2 Indications for use for each target species

For the passive immunisation of neonatal piglets by means of the active immunisation of breeding sows and gilts:

- to prevent mortality and reduce clinical signs and macroscopic lesions caused by *C. difficile,* toxins A and B.
- to reduce clinical signs and macroscopic lesions caused by *C. perfringens* type A, α-toxin.

The reduction of the occurrence of neonatal diarrhoea has been demonstrated under field conditions.

Onset of immunity:
Protection was demonstrated in suckling piglets on the first day of life in challenge studies.

Duration of immunity:
Neutralising protective antibodies transferred via colostrum to the piglets were present up to 28 days after birth in the majority of the piglets.

3.3 Contraindications

Do not use in cases of hypersensitivity to the active substances, to the adjuvant or to any of the excipients.

3.4 Special warnings

Vaccinate healthy animals only.

Protection of piglets is achieved by colostrum intake. Therefore, care should be taken to ensure that each piglet ingests a sufficient quantity of colostrum within the first hours of life.

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:

Not applicable.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Pigs (pregnant sows and gilts):

Common (1 to 10 animals / 100 animals treated):	Injection site inflammation[1] Elevated temperature[2]

[1]Mild local inflammation at the injection site (maximum diameter of 5 cm), which subsided without treatment within 5 days.
[2]A slight transient increase in body temperature (mean 0.27 ºC, in individual pigs up to 0.95 ºC), which subsided without treatment.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a 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.

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 Coli/C. Following administration of the mixed vaccines, an increase in body temperature (mean 1.43 °C, not exceeding 1.87 ºC 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 except the product mentioned above. 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.

Administer the vaccine by deep intramuscular injection in the neck muscles.
Allow the vaccine to reach room temperature (15 °C to 25 °C) before use.
Shake well before use.

Primary vaccination:
Administer one dose (2 ml) at approximately 6 weeks before farrowing and a second dose (2 ml) at approximately 3 weeks before farrowing.
It is recommended that the second dose is given preferably on alternate sides.

Revaccination:
On each subsequent gestation, administer one dose (2 ml) 3 weeks before the expected date of farrowing.

To ensure the correct mixing with Suiseng Coli/C, 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

Zero days.

4. IMMUNOLOGICAL INFORMATION

4.1 ATCvet code: QI09AB12.

The active immunisation of pregnant sows and gilts induces the production of neutralising antibodies against *C. difficile, toxins A and B* and *C. perfringens* type A, α-toxin. These antibodies are transferred via the colostrum to the piglets. The uptake of sufficient colostrum within the first hours of life results in a passive protection of piglets.

Efficacy of the vaccine was demonstrated upon intraperitoneal challenge with *C. difficile* toxin A and B and alpha toxin from *C. perfringens* type A. The efficacy of the vaccine to reduce the occurrence of diarrhoea was demonstrated under field conditions.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product, except with Suiseng Coli/C.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after first opening the immediate packaging: 10 hours.
Shelf life after mixing with Suiseng Coli/C: 10 hours.

5.3 Special precautions for storage

Store and transport refrigerated (2 °C – 8 °C).
Do not freeze.
Protect from light.

5.4 Nature and composition of immediate packaging

20 ml, 50 ml, 100 ml and 250 ml PET bottles, closed with bromobutyl-stoppers and aluminium caps.

Pack sizes

- Cardboard box with 1 PET bottle of 10 doses (20 ml bottle).
- Cardboard box with 1 PET bottle of 10 doses (50 ml bottle)*.
- Cardboard box with 1 PET bottle of 25 doses (50 ml bottle).
- Cardboard box with 1 PET bottle of 25 doses (100 ml bottle)*.
- Cardboard box with 1 PET bottle of 50 doses (100 ml bottle).
- Cardboard box with 1 PET bottle of 50 doses (250 ml bottle)*.
-

* these bottles have sufficient headspace to accommodate the full contents of Suiseng Coli/C if it is intended to mix Suiseng Diff/A and Suiseng Coli/C prior to administration.

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(S)

EU/2/21/278/001-006

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 07/12/2021

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

{DD/MM/YYYY}

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).

ANNEX II

OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

None

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box with 1 PET bottle of 10 doses (20 ml bottle).
Cardboard box with 1 PET bottle of 10 doses (50 ml bottle).
Cardboard box with 1 PET bottle of 25 doses (50 ml bottle).
Cardboard box with 1 PET bottle of 25 doses (100 ml bottle).
Cardboard box with 1 PET bottle of 50 doses (100 ml bottle).
Cardboard box with 1 PET bottle of 50 doses (250 ml bottle).

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Suiseng Diff/A suspension for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each dose (2 ml) contains:

Clostridioides difficile, toxoid A (TcdA)	≥ 1.60 RP*
Clostridioides difficile, toxoid B (TcdB)	≥ 1.65 RP*
Clostridium perfringens type A, α-toxoid	≥ 1.34 RP*

* RP: Relative Potency determined by ELISA

3. PACKAGE SIZE

10 doses (20 ml bottle)
10 doses (50 ml bottle)
25 doses (50 ml bottle)
25 doses (100 ml bottle)
50 doses (100 ml bottle)
50 doses (250 ml bottle)

4. TARGET SPECIES

Pigs (pregnant 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 opened 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

EU/2/21/278/001 (10 doses (20 ml bottle))
EU/2/21/278/002 (10 doses (50 ml bottle))
EU/2/21/278/003 (25 doses (50 ml bottle))
EU/2/21/278/004 (25 doses (100 ml bottle))
EU/2/21/278/005 (50 doses (100 ml bottle))
EU/2/21/278/006 (50 doses (250 ml bottle))

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Bottles of 100 or 250 ml.

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Suiseng Diff/A suspension for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each dose (2 ml) contains:

C. difficile, toxoid A (TcdA)	≥ 1.60 RP*
C. difficile, toxoid B (TcdB)	≥ 1. 65 RP*
C. perfringens type A, α-toxoid	≥ 1.34 RP*

* RP: Relative Potency determined by ELISA

3. TARGET SPECIES

Pigs (pregnant 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 opened 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

25 doses (100 ml bottle)
50 doses (100 ml bottle)
50 doses (250 ml bottle)

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Bottles of 20 or 50 ml.

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Suiseng Diff/A

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Each dose (2 ml) contains:

C. difficile, toxoid A (TcdA)	≥ 1.60 RP*
C. difficile, toxoid B (TcdB)	≥ 1.65 RP*
C. perfringens type A, α-toxoid	≥ 1.34 RP*

* RP: Relative Potency determined by ELISA

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

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

5. PACKAGE SIZE

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

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Suiseng Diff/A suspension for injection for pigs

2. Composition

Each dose (2 ml) contains:

Active substances :

Clostridioides difficile, toxoid A (TcdA)	≥ 1.60 RP*
Clostridioides difficile, toxoid B (TcdB)	≥ 1.65 RP*
Clostridium perfringens type A, α-toxoid	≥ 1.34 RP*

* RP : Relative Potency determined by ELISA

Adjuvants :

Aluminium hydroxide gel	0.6 g

Yellowish-white suspension.

3. Target species

Pigs (pregnant sows and gilts).

4. Indications for use

For the passive immunisation of neonatal piglets by means of the active immunisation of breeding sows and gilts:

- to prevent mortality and reduce clinical signs and macroscopic lesions caused by *C. difficile*, toxins A and B.
- to reduce clinical signs and macroscopic lesions caused by *C. perfringens* type A, α-toxin.

The reduction of the occurrence of neonatal diarrhoea has been demonstrated under field conditions.

Onset of immunity:
Protection was demonstrated in suckling piglets on the first day of life in challenge studies.

Duration of immunity:
Neutralising protective antibodies transferred via colostrum to the piglets were present up to 28 days after birth in the majority of the piglets.

5. Contraindications

Do not use in cases of hypersensitivity to the active substances, to the adjuvant or to any of the excipients.

6. Special warnings

Special warnings:
Vaccinate healthy animals only.
Protection of piglets is achieved by colostrum intake. Therefore, care should be taken to ensure that each piglet ingests a sufficient quantity of colostrum within the first hours of life.

Pregnancy:
Can be used during pregnancy.

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 Coli/C. 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 except the product mentioned above. 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 Coli/C.

7. Adverse events

Pigs (pregnant sows and gilts):

Common (1 to 10 animals / 100 animals treated):	Injection site inflammation[1] Elevated temperature[2]

[1]Mild local inflammation at the injection site (maximum diameter of 5 cm), which subsided without treatment within 5 days.
[2]A slight transient increase in body temperature (mean 0.27 ºC, in individual pigs up to 0.95 ºC), which subsided without treatment.

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 at the end of this leaflet, or via your national reporting system: {national system details}.

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

Intramuscular use.

Administer the vaccine by deep intramuscular injection in the neck muscles.
Dose: 2 ml/animal.

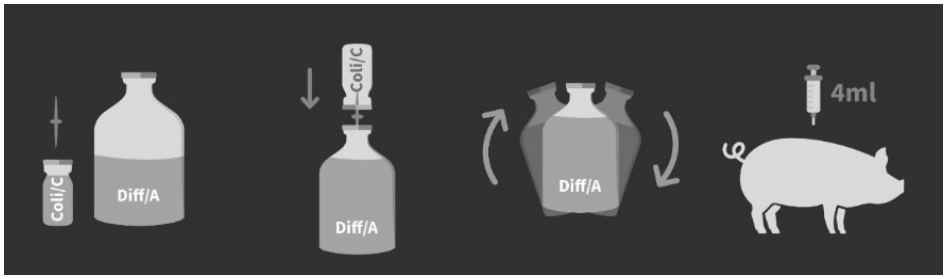
Primary vaccination:
Administer one dose (2 ml) at approximately 6 weeks before farrowing and a second dose (2 ml) at approximately 3 weeks before farrowing.
It is recommended that the second dose is given preferably on alternate sides.

Revaccination:
On each subsequent gestation, administer one dose (2 ml) 3 weeks before the expected date of farrowing.

To ensure the correct mixing with Suiseng Coli/C, 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

Allow the vaccine to reach room temperature (15 °C to 25 °C) before use.
Shake well 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 container: 10 hours.
Shelf life after mixing with Suiseng Coli/C: 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 numbers: EU/2/21/278/001-006

Pack sizes:

Cardboard box with 1 PET bottle of 10 doses (20 ml bottle).
Cardboard box with 1 PET bottle of 10 doses (50 ml bottle)*.
Cardboard box with 1 PET bottle of 25 doses (50 ml bottle).
Cardboard box with 1 PET bottle of 25 doses (100 ml bottle)*.
Cardboard box with 1 PET bottle of 50 doses (100 ml bottle).
Cardboard box with 1 PET bottle of 50 doses (250 ml bottle)*.

* these bottles have sufficient headspace to accommodate the full contents of Suiseng Coli/C if it is intended to mix Suiseng Diff/A and Suiseng Coli/C prior to administration.

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

{DD/MM/YYYY}

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.

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17. Other information

The active immunisation of pregnant sows and gilts induces the production of neutralising antibodies against *C. difficile, toxins A and B* and *C. perfringens* type A, α-toxin. These antibodies are transferred via the colostrum to the piglets. The uptake of sufficient colostrum within the first hours of life results in a passive protection of piglets.

Efficacy of the vaccine was demonstrated upon intraperitoneal challenge with *C. difficile* toxin A and B and alpha toxin from *C. perfringens* type A. The efficacy of the vaccine to reduce the occurrence of diarrhoea was demonstrated under field conditions.