ANNEX II

A. MANUFACTURER OF THE BIOLOGICAL ACTIVE SUBSTANCE AND MANUFACTURER RESPONSIBLE FOR BATCH RELEASE

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

C. STATEMENT OF THE MRLs

A. MANUFACTURER OF THE BIOLOGICAL ACTIVE SUBSTANCE AND MANUFACTURER RESPONSIBLE FOR BATCH RELEASE

Name and address of the manufacturer of the biological active substance

Laboratorios Hipra, S.A.
Avda. la Selva, 135
Amer, 17170 Girona
Spain

Laboratorios Hipra, S.A.
Carretera C-63 km 48.300
Polígono Industrial El Rieral
Amer, 17170 Girona
Spain

Name and address of the manufacturer responsible for batch release

Laboratorios Hipra, S.A.
Avda. la Selva, 135
Amer, 17170 Girona
Spain

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

Veterinary medicinal product subject to prescription.

C. STATEMENT OF THE MRLs

The active substance being a principle of biological origin intended to produce active immunity is not within the scope of Regulation (EC) No 470/2009.

The excipients (including adjuvants) listed in section 6.1 of the SPC are either allowed substances for which table 1 of the annex to Commission Regulation (EU) No 37/2010 indicates that no MRLs are required or are considered as not falling within the scope of Regulation (EC) No 470/2009 when used as in this veterinary medicinal product.

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 for pigs.

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. PHARMACEUTICAL FORM

Suspension for injection.

4. 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)

5. TARGET SPECIES

Pigs (pregnant sows and gilts).

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Intramuscular use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period: Zero days.

9. SPECIAL WARNING(S), IF NECESSARY

10. EXPIRY DATE

EXP {month/year}
Once opened use within 10 hours.

11. SPECIAL STORAGE CONDITIONS

Store and transport refrigerated (2 ºC-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

16. MARKETING AUTHORISATION NUMBER(S)

Vm 17533/5013

17. MANUFACTURER'S BATCH NUMBER

Batch

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 for pigs.

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. PHARMACEUTICAL FORM

Suspension for injection.

4. PACKAGE SIZE

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

5. TARGET SPECIES

Pigs (pregnant sows and gilts).

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Intramuscular use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period: Zero days.

9. SPECIAL WARNING(S), IF NECESSARY

10. EXPIRY DATE

EXP {month/year}
Once opened use within 10 hours.

11. SPECIAL STORAGE CONDITIONS

Store and transport refrigerated (2 ºC-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

16. MARKETING AUTHORISATION NUMBER(S)

Vm 17533/5013

17. MANUFACTURER'S BATCH NUMBER

Batch

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 suspension for injection for pigs.

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

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

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

4. ROUTE(S) OF ADMINISTRATION

Intramuscular use.

5. WITHDRAWAL PERIOD(S)

Withdrawal period: Zero days.

6. BATCH NUMBER

Batch {number}

7. EXPIRY DATE

EXP {month/year}
Once opened use within 10 hours.

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
Suiseng Diff/A 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 43 06 60 - Fax. +34 972 43 06 61
E-mail: hipra@hipra.com

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Suiseng Diff/A suspension for injection for pigs.

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

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	

Yellowish-white suspension.

4. INDICATION(S)

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 substance, to the adjuvant or to any of the excipients.

6. ADVERSE REACTIONS

Mild local inflammation at the injection site (maximum diameter of 5 cm) which subsided without treatment within 5 days was commonly reported in laboratory studies.

A slight transient increase in body temperature (mean 0.27ºC, in individual pigs up to 0.95 ºC) which subsided without treatment occurred commonly in preclinical and field studies.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s)
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

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 inform your veterinary surgeon.

7. TARGET SPECIES

Pigs (pregnant sows and gilts).

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

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.

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 PERIOD(S)

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.
Shelf life after first opening the container: 10 hours.

12. SPECIAL WARNING(S)

Special warnings for each target species:
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.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
None.

Pregnancy and lactation:
Can be used during pregnancy.

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):
None known.

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

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Medicines should not be disposed of via wastewater or household waste.
Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

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).

Not all pack sizes may be marketed.

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.

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

United Kingdom (Northern Ireland)
LABORATORIOS HIPRA, S.A.
Tel: +34 972 43 06 60

Approved 24 November 2021