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	

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Suspension for injection.

Yellowish-white suspension.

4. CLINICAL PARTICULARS

4.1 Target species

Pigs (pregnant sows and gilts).

4.2 Indications for use, specifying the 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.

4.3 Contraindications

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

4.4 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.

4.5 Special precautions for use

Special precautions for use in animals

Not applicable.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

None.

4.6 Adverse reactions (frequency and seriousness)

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 reactions)
- 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).

4.7 Use during pregnancy, lactation or lay

Can be used during pregnancy.

4.8 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

4.9 Amounts to be administered and administration route

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 (2ml) 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.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

None known.

4.11 Withdrawal period(s)

Zero days.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Immunologicals for Suidae, inactivated bacterial vaccines for pigs, clostridium.
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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Aluminium hydroxide gel
Ginseng extract
Simethicone
DEAE-dextran
Disodium phosphate dodecahydrate
Potassium chloride
Potassium dihydrogen phosphate
Sodium chloride
Sodium hydroxide
Water for injections

6.2 Major incompatibilities

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

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 24 months.
Shelf life after first opening the immediate packaging: 10 hours.
Shelf life after mixing with Suiseng Coli/C: 10 hours.

6.4. Special precautions for storage

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

6.5 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.

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 SA
Avda La Selva 135
17170 Amer (Girona)
Spain

8. MARKETING AUTHORISATION NUMBER

Vm 17533/5013

9. DATE OF FIRST AUTHORISATION

24/11/2021

10. DATE OF REVISION OF THE TEXT

July 2024

Gavin Hall

Approved 06 July 2024