SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Salmoporc
Lyophilisate and solvent for suspension for injection / lyophilisate for use in drinking water

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose (1 ml of the reconstituted vaccine) contains:

Active substance:

Salmonella Typhimurium strain 421/125,
(histidine-adenine auxotrophic double marker mutant) 5×10^8 to 5×10^9 CFU*

* Colony Forming Units

Excipients:

Qualitative composition of excipients and other constituents
Lyophilisate:
Sucrose
Bovine serum protein
Solvent:
Sodium chloride
Water for injections

White to yellow-brownish lyophilisate.
Clear colourless solvent.

3. CLINICAL INFORMATION

3.1 Target species

Pigs

3.2 Indications for use for each target species

For active immunisation of piglets of 3 days onwards in order to reduce clinical signs, excretion and invasion of internal organs (mesenteric lymph nodes) after infection with *Salmonella* Typhimurium wild type strains.

For active immunisation of sows in order to reduce the excretion of *Salmonella* Typhimurium wild type strains during lactation. Thus, the possibility of infection of the piglets is reduced.

Onset of immunity: two weeks after the second immunisation.

Duration of immunity: sows 24 weeks, fatteners 19 weeks.

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:

Vaccinated pigs may excrete the vaccine strain up to 42 days following vaccination. The safety of the vaccine strain has been shown for cattle, chickens, geese, ducks, turkeys and pigeons.

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

Since this vaccine contains a live, attenuated microorganism derived from a *Salmonella* Typhimurium wild type strain, appropriate measures should be taken to prevent contamination of the handler and other people that collaborate in the process.

The veterinary medicinal product should not be administered by pregnant women.

Immunocompromised persons are advised to avoid contact with the vaccine and/or vaccinated animals until 42nd day after last vaccination.

Personal protective equipment consisting of disposable gloves should be worn when handling the veterinary medicinal product. Wash and disinfect hands after handling the vaccine.

In case of accidental self-injection, ingestion or spillage onto skin, seek medical advice immediately and show the package leaflet or the label to the physician.

The vaccine strain is sensitive to Ampicillin, Cefotaxime, Chloramphenicol, Ciprofloxacin, Gentamicin, Kanamycin, Oxytetracycline und Streptomycin. The vaccine strain is resistant to Sulfamerazine alone but sensitive to the combination of Sulfamerazine and Trimethoprim.

Drinking water or vaccination equipment should not contain any traces of antibiotics, disinfectant or detergents.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Pigs

Very common (>1 animal / 10 animals treated):	Elevated temperature[1)], Injection site reddening[2)], Injection site swelling[2)]
Common (1 to 10 animals / 100 animals treated):	Diarrhoea[3)]
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Abortion

[1)] Up to 1.1 °C on average, in single cases up to maximum 2.2 °C, up to two days after vaccination.

[2)] Mild, with an average diameter of 4 cm and a maximum diameter of 11 cm. These disappear without treatment within approximately two weeks.
[3)] Mild, after oral application

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 the national competent authority via the national reporting system. See section "Contact details" of the package leaflet.

3.7 Use during pregnancy, lactation or lay

Can be used during pregnancy.

3.8 Interaction with other medicinal products and other forms of interaction

Do not use antimicrobial agents against *Salmonella* spp. five days before and five days after immunisation. Should such a use be indispensable the animals concerned must be revaccinated.

No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product. A decision about using 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

Sows
Basic vaccination:
Two s.c. injections of 1 dose each at an interval of three weeks (approx. six and three weeks before farrowing), but the 2nd vaccination must not be applied at the same site as the 1st vaccination.

Re-vaccination:
One dose s.c., three weeks a.p.

For subcutaneous administration in sows, the freeze-dried contents of an injection vial are to be completely reconstituted in the relevant diluent (1 ml per vaccination dose).
Appearance of the vaccine following reconstitution: aqueous, light greyish to light yellowish, turbid suspension.

Piglets
Two oral vaccinations with 1 dose of 1 ml each at an interval of three weeks from an age of 3 days onwards, administered preferably by drench application using a device suitable for piglets.
For the oral application to piglets the freeze-dried substance of an injection vial with 200 ID should be dissolved in 200 ml of drinking water. It is administered orally as a single application.

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

Following subcutaneous administration of a 10-fold overdose in sows no adverse reactions other than those described under "Adverse events" were observed. Local reactions were commonly observed up to the 21st day after vaccination.
Following oral administration of a 10-fold overdose in piglets, mild diarrhoea, a mild impairment of the general condition as well as a temporary rise in temperature of up to 2 °C and a reduced weight gain were occasionally observed.

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: 6 weeks post 2nd vaccination.

4. IMMUNOLOGICAL INFORMATION

4.1 ATCvet code: QI09AE02

Pharmacotherapeutic group: Immunologicals for suidae, pig, live bacterial vaccines, *Salmonella*

Following oral or subcutaneous vaccination of pigs, the vaccine strain stimulates a local and systemic humoral and cellular immune response against *Salmonella* Typhimurium.

In the case of exposure to *Salmonella* Typhimurium wild type strains, the combined sow/piglet immunisation significantly reduces the colonisation, invasion and excretion of wild type strains in piglets and is therefore especially suitable for minimising the presence of the pathogen in the herd.

The oral administration of the vaccine does not affect the ELISA tests for *Salmonella* in the meat juice in accordance with the guidelines for a program to reduce the introduction of *Salmonella* by means of slaughter pigs into meat production. It should be taken into account that this programme does not apply in all European countries.

Due to the adenine-histidine auxotrophy of the vaccine strain, a differentiation between vaccine and wild type field strains is possible by means of an appropriate growth test such as S-Check.
The vaccine strain can also be distinguished from wild type field strains by molecular biology methods, such as real time Polymerase Chain Reaction (PCR).

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product, except solvent recommended for use with the veterinary medicinal product.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 21 months
Shelf life after reconstitution according to directions: 4 hours

5.3 Special precautions for storage

Store in a refrigerator (2 °C – 8 °C).
Protect from light.

5.4 Nature and composition of immediate packaging

Lyophilisate
Bottles: 10 ml glass vials (type I according to EP)
Stoppers: Rubber stoppers according to EP
Caps: Crimp caps for injection bottles

Solvent
Bottles: 25 ml glass vials (type I according to EP)
Stoppers: Rubber stoppers
Caps: Crimp caps for injection bottles

Pack sizes:
Vaccination of sows: Cardboard box containing 1 vial with 20 doses lyophilised vaccine and 1 vial with 20 ml solvent;
Vaccination of piglets: Cardboard box containing 1 vial with 200 doses

Not all pack sizes may be marketed.

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

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.

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

The original vaccine containers and all vessels used for vaccination must be disinfected after use (disinfectant – except quaternary ammonium bases – in the usual concentrations for use).

6. NAME OF THE MARKETING AUTHORISATION HOLDER

To be completed nationally.

7. MARKETING AUTHORISATION NUMBER(S)

To be completed nationally.

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: {DD/MM/YYYY}
To be completed nationally.

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

To be completed nationally.

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).

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box for 20 doses

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Salmoporc
Lyophilisate and solvent for suspension for injection / lyophilisate for use in drinking water

2. STATEMENT OF ACTIVE SUBSTANCES

1 ml of the reconstituted vaccine contains:

Salmonella Typhimurium strain 421/125, (histidine-adenine auxotrophic double marker mutant) 5×10^8 to 5×10^9 CFU*

* Colony Forming Units

3. PACKAGE SIZE

20 doses
20 ml solvent for suspension for injection

4. TARGET SPECIES

Target species: Pigs

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

For suspension for injection or for use in drinking water.

7. WITHDRAWAL PERIODS

Withdrawal period: Meat and offal: 6 weeks post 2nd vaccination.

8. EXPIRY DATE

Exp. {dd.mm.yyyy}
Once reconstituted use within 4 hours.

9. SPECIAL STORAGE PRECAUTIONS

Store in a refrigerator (2 °C – 8 °C). Protect from light.

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

To be completed nationally.

14. MARKETING AUTHORISATION NUMBERS

To be completed nationally.

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box for 200 doses

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Salmoporc
Lyophilisate for use in drinking water

2. STATEMENT OF ACTIVE SUBSTANCES

1 ml of the reconstituted vaccine contains:

Salmonella Typhimurium strain 421/125, (histidine-adenine auxotrophic double marker mutant) 5×10^8 to 5×10^9 CFU*

* Colony Forming Units

3. PACKAGE SIZE

200 doses

4. TARGET SPECIES

Target species: Pigs

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

For use in drinking water.

7. WITHDRAWAL PERIODS

Withdrawal period: Meat and offal: 6 weeks post 2nd vaccination.

8. EXPIRY DATE

Exp. {dd.mm.yyyy}
Once reconstituted use within 4 hours.

9. SPECIAL STORAGE PRECAUTIONS

Store in a refrigerator (2 °C – 8 °C). Protect from light.

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

To be completed nationally.

14. MARKETING AUTHORISATION NUMBERS

To be completed nationally.

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Vial of 20 doses

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Salmoporc

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Salmonella Typhimurium strain 421/125, double marker mutant (ade-/his-) — 5×10^8 to 5×10^9 CFU/dose

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {dd.mm.yyyy}
Once reconstituted use within 4 hours.

Package size:
20 doses

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Vial of 200 doses

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Salmoporc

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Salmonella Typhimurium strain 421/125, double marker mutant (ade-/his-) 5×10^8 to 5×10^9 CFU/dose

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {dd.mm.yyyy}
Once reconstituted use within 4 hours.

Package size:
200 doses

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Vial of 20 ml solvent for suspension for injection

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Solvent for suspension for injection

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Isotonic sodium chloride solution

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {dd.mm.yyyy}

Package size:
20 ml

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Salmoporc
Lyophilisate and solvent for suspension for injection / lyophilisate for use in drinking water

2. Composition

Each dose (1 ml of the reconstituted vaccine) contains:

Salmonella Typhimurium strain 421/125, (histidine-adenine auxotrophic double marker mutant)	5×10^8 to 5×10^9 CFU*

* Colony Forming Units

White to yellow-brownish lyophilisate.
Clear colourless solvent.

3. Target species

Pigs

4. Indications for use

For active immunisation of piglets of 3 days onwards in order to reduce clinical signs, excretion and invasion of internal organs (mesenteric lymph nodes) after infection with *Salmonella* Typhimurium wild type strains.

For active immunisation of sows in order to reduce the excretion of *Salmonella* Typhimurium wild type strains during lactation. Thus, the possibility of infection of the piglets is reduced.

Onset of immunity: two weeks after the second immunisation.
Duration of immunity: sows 24 weeks, fatteners 19 weeks.

5. Contraindications

None.

6. Special warnings

Special warnings:

Vaccinate healthy animals only.

Special precautions for safe use in the target species:

Vaccinated pigs may excrete the vaccine strain up to 42 days following vaccination. The safety of the vaccine strain has been shown for cattle, chickens, geese, ducks, turkeys and pigeons.

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

Since this vaccine contains a live, attenuated microorganism derived from a *Salmonella* Typhimurium wild type strain, appropriate measures should be taken to prevent contamination of the handler and other people that collaborate in the process.

The veterinary medicinal product should not be administered by pregnant women.

Immunocompromised persons are advised to avoid contact with the vaccine and/or vaccinated animals until 42nd day after last vaccination.

Personal protective equipment consisting of disposable gloves should be worn when handling the veterinary medicinal product. Wash and disinfect hands after handling the vaccine.

In case of accidental self-injection, ingestion or spillage onto skin, seek medical advice immediately and show the package leaflet or the label to the physician.

The vaccine strain is sensitive to Ampicillin, Cefotaxime, Chloramphenicol, Ciprofloxacin, Gentamicin, Kanamycin, Oxytetracycline und Streptomycin. The vaccine strain is resistant to Sulfamerazine alone but sensitive to the combination of Sulfamerazine and Trimethoprim.

Special precautions for the protection of the environment:

Not applicable.

Pregnancy:

Can be used during pregnancy.

Interaction with other medicinal products and other forms of interaction:

Do not use antimicrobial agents against *Salmonella* spp. five days before and five days after immunisation. Should such a use be indispensable the animals concerned must be revaccinated.

No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product. A decision about using this vaccine before or after any other veterinary medicinal product therefore needs to be made on a case by case basis.

Overdose:

Following subcutaneous administration of a 10-fold overdose in sows no adverse reactions other than those described under "Adverse events" were observed. Local reactions were commonly observed up to the 21st day after vaccination.
Following oral administration of a 10-fold overdose in piglets, mild diarrhoea, a mild impairment of the general condition as well as a temporary rise in temperature of up to 2 °C and a reduced weight gain were occasionally observed.

Major incompatibilities:

Do not mix with any other veterinary medicinal product, except solvent recommended for use with the veterinary medicinal product.

7. Adverse events

Pigs

Very common (>1 animal / 10 animals treated):
Elevated temperature[1)], Injection site reddening[2)], Injection site swelling[2)]
Common (1 to 10 animals / 100 animals treated):
Diarrhoea[3)]
Very rare (<1 animal / 10,000 animals treated, including isolated reports):
Abortion

[1)] Up to 1.1 °C on average, in single cases up to maximum 2.2 °C, up to two days after vaccination.
[2)] Mild, with an average diameter of 4 cm and a maximum diameter of 11 cm. These disappear without treatment within approximately two weeks.
[3)] Mild, after oral application.

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 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

Sows
Basic vaccination:
Two s.c. injections of 1 dose each at an interval of three weeks (approx. six and three weeks before farrowing), but the 2nd vaccination must not be applied at the same site as the 1st vaccination.

Re-vaccination:
One dose s.c., three weeks a.p.

Piglets
Two oral vaccinations with 1 dose of 1 ml each at an interval of three weeks from an age of 3 days onwards.

9. Advice on correct administration

Instructions for correct administration:

For subcutaneous administration in sows, the freeze-dried contents of an injection vial are to be completely reconstituted in the relevant solvent (1 ml per vaccination dose).

For the oral application to piglets the freeze-dried substance of an injection vial with 200 ID should be dissolved in 200 ml of drinking water. It is administered orally as a single application preferably by drench application using a device suitable for piglets.

Drinking water and vaccination equipment should not contain any traces of antibiotics, disinfectant or detergents.

Due to the adenine-histidine auxotrophy of the vaccine strain, a differentiation between vaccine and wild type field strains is possible by means of an appropriate growth test such as S-Check.
The vaccine strain can also be distinguished from wild type field strains by molecular biology methods, such as real time Polymerase Chain Reaction (PCR).

Appearance after reconstitution: aqueous, light greyish to light yellowish, turbid suspension.

10. Withdrawal periods

Meat and offal: 6 weeks post 2nd vaccination.

11. Special storage precautions

Keep out of the sight and reach of children.

Store in a refrigerator (2 °C – 8 °C). Protect from light.

Do not use this veterinary medicinal product after the expiry date which is stated on the label and carton after Exp.

Shelf life after reconstitution according to directions: 4 hours.

12. Special precautions for disposal

The original vaccine containers and all vessels used for vaccination must be disinfected after use (disinfectant – except quaternary ammonium bases – in the usual concentrations for use).

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.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

MA number: To be completed nationally.

Pack sizes:
Vaccination of sows: Cardboard box containing 1 vial with 20 doses lyophilised vaccine and 1 vial with 20 ml solvent;
Vaccination of piglets: Cardboard box containing 1 vial with 200 doses

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

To be completed nationally.

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 contact details to report suspected adverse reactions:
To be completed nationally.

Manufacturer responsible for batch release:
IDT Biologika GmbH
Am Pharmapark
06861 Dessau-Rosslau
Germany

Ceva-Phylaxia Veterinary Biologicals Co. Ltd.
Szállás u. 5.
1107 Budapest
Hungary

17. Other information

Immunological properties:
Following oral or subcutaneous vaccination of pigs, the vaccine strain stimulates a local and systemic humoral and cellular immune response against *Salmonella* Typhimurium.

In the case of exposure to *Salmonella* Typhimurium wild type strains, the combined sow/piglet immunisation significantly reduces the colonisation, invasion and excretion of wild type strains in piglets and is therefore especially suitable for minimising the presence of the pathogen in the herd.

The oral administration of the vaccine does not affect the ELISA tests for *Salmonella* in the meat juice in accordance with the guidelines for a program to reduce the introduction of *Salmonella* by means of slaughter pigs into meat production. It should be taken into account that this programme does not apply in all European countries.