SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Salmoporc lyophilisate and solvent for suspension for injection and for oral suspension for pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1 ml dose contains:

Active substances:

Salmonella enterica, subsp*. enterica,* serovar Typhimurium, strain 421/125 (histidine-adenine auxotrophic), live 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

Subcutaneous use:
For the active immunisation of pregnant sows and gilts to reduce excretion of *Salmonella* Typhimurium wild type strains during lactation.

Onset of immunity: 2 weeks after the second vaccination.
Duration of immunity: 24 weeks after the second vaccination.

Oral use:
For active immunisation of suckling and weaned piglets to reduce bacterial colonisation and excretion as well as clinical symptoms due to an infection with *Salmonella* Typhimurium.
Onset of immunity: 2 weeks after the second vaccination.
Duration of immunity: 19 weeks after the second vaccination.

3.3 Contraindications

None.

3.4 Special warnings

Vaccinate healthy animals only.

Do not use antimicrobial agents against *Salmonella* spp. 5 days before and 5 days after vaccination.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Vaccinated pigs may excrete the vaccine strain up to 20 days following vaccination. The vaccine may thus spread to susceptible pigs in contact with vaccinated pigs. During this time, pigs intended for slaughter should not come into contact with vaccinated pigs.

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

In case of accidental self-injection or ingestion and in case the vaccine comes into contact with a mucous membrane, seek medical advice immediately and show the package leaflet or the label to the physician.
Personal protective equipment consisting of disposable gloves should be worn when handling the veterinary medicinal product.
Since this vaccine has been prepared with live, attenuated microorganisms, appropriate measures should be taken to prevent contamination of the handler and other people that collaborate in the process.
Immunocompromised persons should avoid contact with the product and vaccinated animals.
The vaccine strain can be found in the environment for up to 20 days post vaccination.
Personnel involved in attending vaccinated pigs should follow general hygiene principles (changing clothes, wearing gloves, cleaning and disinfection of boots) and take particular care in handling animal waste and bedding materials from recently vaccinated pigs.

The vaccine strain is sensitive to ampicillin, cefotaxime, chloramphenicol, ciprofloxacin, gentamycin, kanamycin, oxytetracycline and streptomycin. The vaccine strain is resistant to sulfamerazine alone but sensitive to the combination of sulfamerazine and trimethoprim.

It is possible to distinguish between the attenuated vaccine strain and *Salmonella* Typhimurium wild type strains using an appropriate growth test such as the Ceva S-Check test.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Target species: Pigs (sows and gilts)

Very common (> 1 animal / 10 animals treated):	Elevated temperature[1], Injection site reddening[2], Injection site swelling[2]

[1] Transient, 1.1 °C on average, in single cases up to maximum 2.2 °C, up to 2 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.

Target species: Pigs (suckling piglets)

Common (1 to 10 animals / 100 animals treated):	Diarrhoea[1]

[1] Mild, after oral administration.

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 the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy:

Can be used during pregnancy.

Fertility:

The vaccine has not been tested in adult male pigs for reproduction.

3.8 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 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

Subcutaneous use in pregnant sows and gilts and oral use in suckling and weaned piglets.

Preparation of vaccine for subcutaneous and oral use (reconstitution):
Reconstitute the lyophilisate by adding the full content of the solvent at room temperature.
Ensure that the lyophilisate is completely reconstituted before use.
The reconstituted vaccine is an aqueous, light greyish to light yellowish, turbid suspension.
Avoid multiple broaching.

Vaccination scheme for subcutaneous use in gilts and sows:
Primary vaccination: Two subcutaneous injections of 1 dose of 1 ml each at an interval of three weeks (approx. six and three weeks before the expected farrowing).
The second vaccination must not be applied at the same site as the first vaccination.
Re-vaccination: 1 dose subcutaneously, three weeks before farrowing.

Vaccination scheme for oral use in suckling piglets and weaned 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 by drench 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 events 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 was commonly observed and a mild impairment of the general condition as well as a rise in temperature of up to 2 °C that lasted for max. 24 hours were very commonly observed.
Vaccination with an overdose may result in a transient impairment of growth rate in the immediate period after administration of the vaccine.

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 .

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QI09AE02

Following oral or subcutaneous vaccination of pigs the vaccine strain stimulates active immunity against *Salmonella* Typhimurium.

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.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product, except solvent supplied 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
Containers: 10 ml glass vials (type I) containing 20 doses of lyophilisate
Stoppers: Rubber stoppers
Caps: Aluminium crimp caps.

Solvent
Containers: 25 ml glass vials (type I) containing 20 ml of solvent
Stoppers: Rubber stoppers
Caps: Aluminium crimp caps.

Pack sizes:
Cardboard box containing 1 vial with 20 doses lyophilised vaccine and 1 vial with 20 ml solvent.

5.5 Special precautions for the disposal of unused veterinary medicinal product 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

Ceva Sante Animale

7. MARKETING AUTHORISATION NUMBERS

Vm 14966/5051 (GB)
Vm 14966/3050 (NI)

8. DATE OF FIRST AUTHORISATION

18 April 2019

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

April 2026

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.
Find more product information by searching for the 'Product Information Database' on www.gov.uk.

Gavin Hall

Approved: 08 May 2026