Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Salmoporc lyophilisate and solvent for suspension for injection for pigs

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

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

Active substance:
Salmonella Typhimurium mutant, strain 421/125, genetically-stable, double-attenuated (histidine-adenine auxotrophic) 5×10^8 to 5×10^9 CFU*

* Colony Forming Units

Excipients:
For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Lyophilisate and solvent for suspension for injection

White to yellow-brownish lyophilisate
Clear colourless solvent

4 CLINICAL PARTICULARS

4.1 Target Species

Pigs

4.2 Indications for use, specifying the target species

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

Onset of immunity: two 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: two weeks after the second vaccination
Duration of immunity: 19 weeks after the second vaccination

4.3 Contraindications

None.

4.4 Special warnings for each target species

Vaccinate healthy animals only.

The vaccine has not been tested in breeding boars.

Do not use antimicrobial agents against *Salmonella* spp. five days before and five days after immunisation.

4.5 Special precautions for use

Special precautions for use in animals
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 und 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 the IDT Salmonella Diagnostic Kit.

4.6 Adverse reactions (frequency and seriousness)

A temporary rise in body temperature by up to 1.1 °C on average, in single cases up to maximum 2.2 °C (up to two days after vaccination) occurs very commonly after vaccination of gilts and sows.
A mild local reaction (redness and swelling with an average diameter of 4 cm and a maximum diameter of 11 cm) at the injection site occurs very commonly in gilts and sows. These disappear without treatment within approximately two weeks.
Mild diarrhea was commonly observed in suckling piglets after oral application.

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).

4.7 Use during pregnancy, lactation or lay

Pregnancy
The vaccine can be used during pregnancy.

4.8 Interaction with other medicinal products and other forms of interactions

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.

4.9 Amounts to be administered and administration route

For the subcutaneous use in gilts and sows and for the oral use in 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.

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

Following subcutaneous administration of a 10-fold overdose in sows no adverse reactions other than those described under "Adverse reactions" 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 diarrhea 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.

4.11 Withdrawal period(s)

Meat and offal: 6 weeks post 2nd vaccination.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

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

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lyophilisate:
Sucrose
Bovine serum protein

Solvent:
Sodium chloride
Water for injections

6.2 Major incompatibilities

Do not mix with any other veterinary medicinal product, except the corresponding solvent.

6.3 Shelf-life

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

6.4 Special precautions for storage

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

6.5 Nature and composition of immediate packaging

Lyophilisate
Bottles: 10 ml glass vials (type I) containing 20 doses of lyophilisate
Stoppers: Rubber stoppers
Caps: Aluminium crimp caps

Solvent
Bottles: 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

6.6 Special precautions for the disposal of unused veterinary medicinal products 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

Ceva Santé Animale
10, avenue de La Ballastière
33500 Libourne
France

8 MARKETING AUTHORISATION NUMBER(S)

VPA10815/064/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 18 April 2019

10 DATE OF REVISION OF THE TEXT

December 2020