Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Salmoporc lyophilisate for oral suspension 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 for oral suspension

White to yellow-brownish lyophilisate

4 CLINICAL PARTICULARS

4.1 Target Species

Pigs

4.2 Indications for use, specifying the target species

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.
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 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)

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

Not applicable.

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 oral use in piglets.

Preparation of the vaccine for use (reconstitution):
Fill a clean bottle with 200 ml of water. Bottle and water should not contain any residues of antimicrobials, detergents or disinfectants. Reconstitute the lyophilisate by transfering an appropriate amount of water from the bottle to the lyophilisate. Ensure that the lyophilisate is completely reconstituted before transferring the whole content back to the bottle filled with water. Shake well and use within 4 hours.
The reconstituted vaccine is an aqueous, light greyish to light yellow, turbid suspension.
Avoid multiple broaching.

Oral vaccination:
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 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 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

Sucrose
Bovine serum protein

6.2 Major incompatibilities

Do not mix with any other veterinary medicinal product.

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

Bottles: 10 ml glass vials (type I) containing 200 doses of lyophilisate
Stoppers: Rubber stoppers
Caps: Aluminium crimp caps

Pack sizes:
Cardboard box containing 1 vial with 200 doses lyophilised vaccine

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)

VPA10815/064/002

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