## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Salmoporc lyophilisate 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 $5 \times 10^8$ to $5 \times 10^9$ CFU*

* Colony Forming Units

**Excipients:**

| **Qualitative composition of excipients and other constituents** |
|---|
| Sucrose |
| Bovine serum protein |

White to yellow-brownish lyophilisate.

## 3. CLINICAL INFORMATION

### 3.1 Target species

Pigs

### 3.2 Indications for use for each target species

For the 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 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 (suckling and weaned piglets)

| | |
|---|---|
| Common<br>(1 to 10 animals / 100 animals treated): | Diarrhoea[1] |

[1] Mild and after administration to suckling piglets only.

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

Not applicable.

### 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 to use 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

Oral use in suckling and weaned 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 transferring an appropriate amount of water from the bottle to the lyophilisate. Ensure that the lyophilisate is completely reconstituted before transferring the whole content back into the bottle filled with water. Shake well before use.
The reconstituted vaccine is an aqueous, light greyish to light yellow, turbid suspension.

Vaccination scheme:
Two oral vaccinations with 1 dose of 1 ml each at an interval of 3 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 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. IMMUNOLOGICAL INFORMATION

### 4.1 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.

## 5. PHARMACEUTICAL PARTICULARS

### 5.1 Major incompatibilities

Do not mix with any other 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

Container: 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.

### 5.5 Special precautions for the disposal of unused veterinary medicinal products 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 Santé Animale,

## 7. MARKETING AUTHORISATION NUMBER(S)

VPA10815/064/002

## 8. DATE OF FIRST AUTHORISATION

18/04/2019

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

03/04/2026

## 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).