ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box for 200 doses

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Salmoporc, lyophilisate for oral suspension for pigs

2. STATEMENT OF ACTIVE SUBSTANCES

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

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

* Colony Forming Units

3. PHARMACEUTICAL FORM

Lyophilisate for oral suspension

4. PACKAGE SIZE

200 doses

5. TARGET SPECIES

Pigs

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

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

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Once reconstituted use within 4 hours.

11. SPECIAL STORAGE CONDITIONS

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

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only.
To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Ceva Animal Health Ltd
Explorer House
Mercury Park
Wycombe Lane
Wooburn Green
High Wycombe
Buckinghamshire
HP10 0HH
United Kingdom

16. MARKETING AUTHORISATION NUMBER

Vm 15052/4162

17. MANUFACTURER'S BATCH NUMBER

Lot:

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Vial of 200 doses

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Salmoporc, lyophilisate for oral suspension for pigs

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

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

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

200 doses

4. ROUTE(S) OF ADMINISTRATION

Oral

5. WITHDRAWAL PERIOD(S)

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

6. BATCH NUMBER

Lot:

7. EXPIRY DATE

EXP {month/year}
Once reconstituted use within 4 hours.

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:

Salmoporc
Lyophilisate for oral suspension for pigs

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:

Ceva Animal Health Ltd
Explorer House
Mercury Park
Wycombe Lane
Wooburn Green
High Wycombe
Buckinghamshire
HP10 0HH
United Kingdom

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Salmoporc, lyophilisate for oral suspension for pigs

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

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

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

* Colony Forming Units

4. INDICATION

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

5. CONTRAINDICATIONS

None.

6. ADVERSE REACTIONS

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).

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 inform your veterinary surgeon.

Alternatively you can report via your national reporting system {national system details}.

7. TARGET SPECIES

Pigs

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

For the oral use in piglets.

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.

9. ADVICE ON CORRECT ADMINISTRATION

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.

10. WITHDRAWAL PERIOD

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.
Shelf life after reconstitution according to directions: 4 hours.

12. SPECIAL WARNING(S)

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.

It is possible to distinguish between the attenuated vaccine strain and *Salmonella* Typhimurium wild type strains using the IDT Salmonella Diagnostic Kit.

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:
Caution – live vaccine.
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 is resistant to Sulfamerazine alone but sensitive to the combination of Sulfamerazine and Trimethoprim.

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.

Overdose (symptoms, emergency procedures, antidotes):
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.

Incompatibilities:
Do not mix with any other veterinary medicinal product.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Medicines should not be disposed of via wastewater or household waste.
Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.
These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

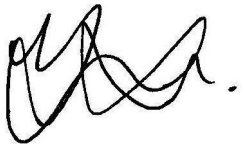
October 2022

15. OTHER INFORMATION

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

Immunological properties:
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 for reducing the introduction of *Salmonella* by means of slaughter pigs into meat production.



Approved: 18 August 2023