ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box for 20 doses

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Salmoporc lyophilisate and solvent for suspension for injection 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 x 10^8 to 5 x 10^9 CFU*

* Colony Forming Units

3. PHARMACEUTICAL FORM

Lyophilisate and solvent for suspension for injection

4. PACKAGE SIZE

20 doses
20 ml solvent for reconstitution

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 15052/4161

17. MANUFACTURER'S BATCH NUMBER

Lot:

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Vial of 20 doses

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Salmoporc lyophilisate for suspension for injection 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

20 doses

4. ROUTE(S) OF ADMINISTRATION

SC

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.

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Vial of 20 ml solvent for reconstitution

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Solvent for Salmoporc
Isotonic sodium chloride solution

2. STATEMENT OF ACTIVE SUBSTANCES

3. PHARMACEUTICAL FORM

4. PACKAGE SIZE

20 ml

5. TARGET SPECIES

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

Protect from light.

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

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

For animal treatment only.

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 15052/4161

17. MANUFACTURER'S BATCH NUMBER

Lot:

B. PACKAGE LEAFLET

PACKAGE LEAFLET:

Salmoporc

Lyophilisate and solvent for suspension for injection 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 and solvent for suspension for injection 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

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

5. CONTRAINDICATIONS

None.

6. ADVERSE REACTIONS

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 site of injection 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).

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

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.

9. ADVICE ON CORRECT ADMINISTRATION

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.

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.
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.

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 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 is resistant to Sulfamerazine alone but sensitive to the combination of Sulfamerazine and Trimethoprim.

Pregnancy:
The vaccine can be used during pregnancy.

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 subcutaneous administration of a 10-fold overdose in sows no adverse events 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.

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

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

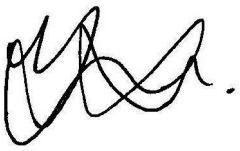
October 2022

15. OTHER INFORMATION

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

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



Approved: 18 August 2023