ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cevac Salmune ETI K suspension for injection for chickens

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose (0.5 ml) of vaccine contains:

Active substances:

Salmonella enterica, subsp. *enterica*, serovar Enteritidis, strain 038-90, inactivated at least 122 ELISA units*
Salmonella enterica, subsp. *enterica*, serovar Typhimurium, strain 076-94, inactivated at least 212 ELISA units*
Salmonella enterica, subsp. *enterica*, serovar Infantis, strain SM-595, inactivated at least 157 ELISA units*

* as measured by *in vitro* potency assay.

Adjuvant:

Aluminium hydroxide gel (as Al^{3+}) 1.3 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Thiomersal	0.05 mg
Trometamol (TRIS)	
Maleic acid	
Sodium chloride	
Sodium hydroxide	
Water for injections	

Greyish-white or yellowish-white suspension, sedimentation may occur, homogenous after shaking.

3. CLINICAL INFORMATION

3.1 Target species

Chickens (breeders and layers).

3.2 Indications for use for each target species

For the active immunisation of chickens (breeders and layers) from 10 weeks of age to reduce faecal excretion of *Salmonella* Enteritidis, *Salmonella* Typhimurium and *Salmonella* Infantis.

Salmonella Enteritidis:
Onset of immunity: 4 weeks after 2nd vaccination
Duration of immunity: 69 weeks after 2nd vaccination

Salmonella Typhimurium:
Onset of immunity: 4 weeks after 2nd vaccination

Duration of immunity: 71 weeks after 2nd vaccination

Salmonella Infantis:
Onset of immunity: 4 weeks after 2nd vaccination
Duration of immunity: 44 weeks after 2nd vaccination

3.3 Contraindications

None.

3.4 Special warnings

Vaccinate healthy animals only.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Not applicable.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Chickens:

Very common (>1 animal / 10 animals treated):	Injection site reaction*

*Yellow discolouration in breast muscle four weeks after the second vaccination.

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

Do not use in birds in lay and within 4 weeks before the start of the laying period.

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

Intramuscular use.

Two vaccinations into breast muscle, each of 0.5 ml, with an interval of four weeks, should be given.

The recommended age for the first vaccination is from 10 weeks. Second vaccination should be given no later than 4 weeks before the onset of lay.

Shake well before use.
Apply usual aseptic procedures.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

Not applicable.

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

Any person intending to manufacture, import, possess, distribute, sell, supply and use this veterinary medicinal product must first consult the relevant Member State's competent authority on the current vaccination policies, as these activities may be prohibited in a Member State on the whole or part of its territory pursuant to national legislation.

3.12 Withdrawal periods

Zero days.

4. IMMUNOLOGICAL INFORMATION

4.1 ATCvet code: QI01AB01

Inactivated bacterial vaccine (salmonella) for domestic fowl.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after first opening the immediate packaging: 10 hours.

5.3 Special precautions for storage

Store and transport refrigerated (2 °C – 8 °C).
Do not freeze.

Protect from light.

5.4 Nature and composition of immediate packaging

Low density polyethylene (LDPE) bottle sealed with bromobutyl rubber stopper and aluminium-plastic cap, in carton box.

1 x 500 ml /1000 doses

5 x 500 ml /5 x 1000 doses

Not all pack sizes may be marketed.

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-Phylaxia Co. Ltd.

7. MARKETING AUTHORISATION NUMBER(S)

EU/2/24/320/001-002

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 30/08/2024.

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

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).

ANNEX II

OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

None

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton box, 1 x 1000 doses, 5 x 1000 doses

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cevac Salmune ETI K suspension for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each dose (0.5 ml) of vaccine contains:

Salmonella Enteritidis, strain 038-90, inactivated	at least 122 ELISA units*
Salmonella Typhimurium, strain 076-94, inactivated	at least 212 ELISA units*
Salmonella Infantis, strain SM-595, inactivated	at least 157 ELISA units*

* as measured by *in vitro* potency assay.

3. PACKAGE SIZE

1 x 500 ml /1000 doses
5 x 500 ml /5 x 1000 doses

4. TARGET SPECIES

Chickens (breeders and layers)

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Intramuscular use.

7. WITHDRAWAL PERIODS

Withdrawal period: Zero days.

8. EXPIRY DATE

Exp. {dd/mm/yyyy}

Once opened use within 10 hours.

9. SPECIAL STORAGE PRECAUTIONS

Store and transport refrigerated.

Do not freeze.

Protect from light.

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

11. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

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

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Ceva-Phylaxia Co. Ltd.

14. MARKETING AUTHORISATION NUMBERS

EU/2/24/320/001 1 x 500 ml /1000 doses
EU/2/24/320/002 5 x 500 ml /5 x 1000 doses

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

LDPE bottle, 1 x 1000 doses, 5 x 1000 doses

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cevac Salmune ETI K suspension for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each dose (0.5 ml) of vaccine contains:

Salmonella Enteritidis, strain 038-90, inactivated	min.122 ELISA units
Salmonella Typhimurium, strain 076-94, inactivated	min. 212 ELISA units
Salmonella Infantis, strain SM-595, inactivated	min. 157 ELISA units

3. TARGET SPECIES

Chickens (breeders and layers)

4. ROUTES OF ADMINISTRATION

Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal period: Zero days

6. EXPIRY DATE

Exp. {dd/mm/yyyy}

Once opened use within 10 hours.

7. SPECIAL STORAGE PRECAUTIONS

Store and transport refrigerated.
Do not freeze.

Protect from light.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Ceva-Phylaxia Co. Ltd.

9. BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Cevac Salmune ETI K suspension for injection for chickens

2. Composition

Each dose (0.5 ml) of vaccine contains:

Active substances:

Salmonella enterica, subsp. *enterica,* inactivated	
serovar Enteritidis, strain 038-90	at least 122 ELISA units*
serovar Typhimurium, strain 076-94	at least 212 ELISA units*
serovar Infantis, strain SM-595	at least 157 ELISA units*

* as measured by *in vitro* potency assay.

Adjuvant:

Aluminium hydroxide gel (as Al^{3+})	1.3 mg

Excipients:

Thiomersal:	0.05 mg

Greyish-white or yellowish-white suspension, sedimentation may occur, homogenous after shaking.

3. Target species

Chickens (breeders and layers)

4. Indications for use

For the active immunisation of chickens (breeders and layers) from 10 weeks of age to reduce faecal excretion of *Salmonella* Enteritidis, *Salmonella* Typhimurium and *Salmonella* Infantis.

Salmonella Enteritidis:
Onset of immunity: 4 weeks after 2nd vaccination
Duration of immunity: 69 weeks after 2nd vaccination

Salmonella Typhimurium:
Onset of immunity: 4 weeks after 2nd vaccination
Duration of immunity: 71 weeks after 2nd vaccination

Salmonella Infantis:
Onset of immunity: 4 weeks after 2nd vaccination
Duration of immunity: 44 weeks after 2nd vaccination

5. Contraindications

None.

6. Special warnings

Special warnings:
Vaccinate healthy animals only.

Special precautions for safe use in the target species:
Not applicable.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

Laying birds:
Do not use in birds in lay and within 4 weeks before the start of the laying period.

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.

Special restrictions for use and special conditions for use:
Any person intending to manufacture, import, possess, distribute, sell, supply and use this veterinary medicinal product must first consult the relevant Member State's competent authority on the current vaccination policies, as these activities may be prohibited in a Member State on the whole or part of its territory pursuant to national legislation.

Major incompatibilities:
In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

7. Adverse events

Chickens:
Very common (>1 animal / 10 animals treated): Injection site reaction*.
*Yellow discolouration in breast muscle four weeks after the second vaccination.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. 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 contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system: {national system details}.

8. Dosage for each species, routes and method of administration

Intramuscular use.

Two vaccinations into breast muscle, each of 0.5 ml, with an interval of four weeks, should be given. The recommended age for the first vaccination is from 10 weeks. Second vaccination should be given no later than 4 weeks before the onset of lay.

9. Advice on correct administration

Shake well before use.
Apply usual aseptic procedures.

10. Withdrawal periods

Zero days.

11. Special storage precautions

Keep out of the sight and reach of children.

Store and transport refrigerated (2 ºC – 8 ºC).
Do not freeze.

Protect from light.

Do not use this veterinary medicinal product after the expiry date which is stated on the carton and bottle label after Exp.

Shelf life after first opening the immediate packaging: 10 hours.

12. Special precautions for disposal

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 applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

EU/2/24/320/001-002

Low density polyethylene (LDPE) bottle sealed with bromobutyl rubber stopper and aluminium-plastic cap, in carton box.
1 x 500 ml /1000 doses
5 x 500 ml /5 x 1000 doses

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

Detailed information on this veterinary medicinal product is available in the Union Product Database (*https://medicines.health.europa.eu/veterinary*).

16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release and contact details to report suspected adverse reactions:

Ceva-Phylaxia Co. Ltd.
1107 Budapest, Szállás u. 5.
Hungary

Tel.: + 00 800 35 22 11 51
E-mail: pharmacovigilance@ceva.com