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 $Al^{3}+$) 1.3g

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 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

Not applicable.

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 product 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 Animal Health Ltd

7. MARKETING AUTHORISATION NUMBER

Vm 15052/5050

8. DATE OF FIRST AUTHORISATION

24 December 2024

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

December 2024

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

Find more product information by searching for the 'Product Information Database' or 'PID' on www.gov.uk.

Gavin Hall

Approved: 25 March 2025