

PARTICULARS TO APPEAR ON THE OUTER PACKAGE {NATURE/TYPE}

1 x 1000 doses, 5 x 1000 doses carton box

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:

<i>Salmonella</i> Enteritidis, strain 038-90, inactivated	at least 122 ELISA units*
<i>Salmonella</i> Typhimurium, strain 076-94, inactivated	at least 212 ELISA units*
<i>Salmonella</i> 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. INDICATION(S)

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 Animal Health Ltd

14. MARKETING AUTHORISATION NUMBERS

Vm 15052/5050

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:

<i>Salmonella</i> Enteritidis, strain 038-90, inactivated	min. 122 ELISA units
<i>Salmonella</i> Typhimurium, strain 076-94, inactivated	min. 212 ELISA units
<i>Salmonella</i> 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 Animal Health Ltd

9. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE 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 Al³⁺) 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 the 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:

Not applicable.

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 at:

Website: <https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine>

e-mail: adverse.events@vmd.gov.uk

8. DOSAGE FOR EACH SPECIES, ROUTE(S) 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 °C – 8 °C).
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

Vm 15052/5050

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/1000 doses

Not all pack sizes may be marketed.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

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

16. CONTACT DETAILS

Marketing authorisation holder and contact details to report suspected adverse reactions:

Ceva Animal Health Ltd
Explorer House
Mercury Park
Wycombe Lane
Wooburn Green
High Wycombe
Buckinghamshire
HP10 0HH
01628 334056
technicalandpvuk-group@ceva.com

Tel.: + 00 800 35 22 11 51

E-mail: pharmacovigilance@ceva.com

Manufacturer responsible for batch release:

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

17. OTHER INFORMATION

POM-V

Gavin Hall

Approved: 25 March 2025