SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINE

CEVAC MEGAMUNE K INJECTABLE EMULSION FOR CHICKENS

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

A 0.5 mL dose contains:

Active substances:

Inactivated Newcastle disease virus, strain "SZ" La Sota ……	≥ 18.6 EU*
Inactivated avian infectious bronchitis virus, strain M-41 ……	≥ 5.3 $\log_2$ HI title**
Inactivated avian infectious bronchitis virus, QX Fr strain and M-41 strain……	≥ 35.2 EU*/***
Inactivated egg drop syndrome virus, strain B8/78 …….....	≥ 8.0 $\log_2$ HI title**
Inactivated avian metapneumovirus, strain TRT50 …….....	≥ 26.4 EU*

* ELISA antigen unit evaluated in the activity test
** Hemagglutination inhibition titer in the activity test
*** Single title for the 2 strains which are not distinguished by the activity test performed

Adjuvant:

Light liquid paraffin ……	0.270 mL

Excipient(s):

Qualitative composition of excipients and other components	Quantitative composition if this information is essential for the proper administration of the veterinary medicinal product
Sorbitan oleate	/
Polysorbate 80	/
Thiomersal	10 µg
Phosphate buffer solution	/

After shaking, the vaccine should be a homogeneous, off-white emulsion.

3. CLINICAL INFORMATION

3.1 Target species

Hens (future laying and breeding pullets).

3.2 Indications for use for each target species

Cevac Megamune K is recommended for vaccinating flocks of future laying and breeding pullets, in order to:

- reduce mortality, clinical signs, lesions caused by the Newcastle disease virus;

- reduce egg drop, respiratory signs and virus excretion caused by Massachusetts serotypes and QX strain of infectious bronchitis virus;

- reduce the drop in egg production caused by the egg drop syndrome virus;

- reduce respiratory signs and viral shedding caused by avian metapneumovirus.

Onset of immunity: NDV: 3 weeks after vaccination.

IBV, EDSV and AMPV: 4 weeks after vaccination.

Duration of immunity: NDV and AMPV: 46 weeks after vaccination.

IBV QX: 43 weeks after vaccination.

IBV M-41: 28 weeks after vaccination to deduce the drop in egg production and 43 weeks after vaccination to reduce respiratory signs.

EDSV: 68 weeks after vaccination.

Cevac Megamune K is intended for use as a booster vaccination following primary vaccination with live vaccines against infectious bronchitis and avian metapneumovirus.

The onset and duration of immunity have been demonstrated for the Cevac Megamune K vaccine in properly pre-immunized birds. Birds should be pre-immunized twice with the Massachusetts and 793/B group IB live vaccines and once with the AMP subtype B live vaccine, preferably the one from Ceva Santé Animale.

Vaccination with Cevac Megamune K must be administered no later than 9 weeks after vaccination with live vaccines.

3.3 Contraindications

None.

3.4 Special warnings

Vaccinate only healthy animals.

3.5 Special precautions for use

Special precautions for safe use in target species

Not applicable.

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

For the user:

This veterinary medicinal product contains mineral oil. Accidental (self-)injection can cause severe pain and swelling, particularly if (self-)injected into a joint or finger, and, in rare cases, lead to the loss of the finger if a medical examination is not performed promptly. In the event of accidental (self-)injection with this veterinary medicinal product, even in a small amount, seek medical advice immediately and show the package leaflet to the doctor. If the pain persists for more than 12 hours after the medical examination, consult the doctor again.

For the doctor:

This veterinary medicinal product contains mineral oil. Even a small amount of this product, if accidentally injected, can cause severe swelling that may lead to ischemic necrosis or even the loss of a toe. Immediate surgical intervention by a specialist is imperative. Rapid incision and irrigation of the injected area may be necessary, particularly if soft tissue or a tendon of a toe is affected.

Special precautions regarding environmental protection

Not applicable.

Other precautions

3.6 Side effects

Chickens.

Frequent (1 to 10 animals / 100 animals treated):	Redness at injection site [1].

[1] This reaction disappears in 1 day.

It is important to report adverse reactions. Reporting allows for ongoing monitoring of the safety of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, either to the marketing authorization holder or their local representative, or to the competent national authority via the national reporting system. See also the relevant section of the package leaflet for contact details.

3.7 Use during pregnancy, lactation or egg-laying

Egg-laying birds :

Do not use on birds during the laying period and during the 3 weeks preceding the laying period.

3.8 Drug interactions and other forms of interaction

No information is available regarding the safety and efficacy of this vaccine when used with any other veterinary medicinal product. Therefore, the decision to use this vaccine before or after another veterinary medicinal product should be made on a case-by-case basis.

3.9 Routes of administration and dosage

Cevac Megamune K should be administered from 14 weeks of age but no later than 3 weeks before the expected start of the laying period.

The vaccine dose is 0.5 mL, injected intramuscularly (into the chest muscles).

Store the vaccine at room temperature (15 to 25°C) for 3 to 4 hours before use. Shake the vial well before use. Use sterile injection equipment. Check the syringe for accuracy to ensure the correct dose is delivered. Once opened, the contents must be used within 10 hours; otherwise, it must be discarded.

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

Not applicable.

3.11 Specific restrictions on use and special conditions of use, including restrictions related to the use of veterinary antimicrobial and antiparasitic medicinal products in order to reduce the risk of the development of resistance

Not applicable.

3.12 Waiting Time

Zero days.

4. Immunological Information

4.1 ATCvet Code

QI01AA18.

The vaccine is intended to stimulate active immunity against avian rhinotracheitis virus, infectious bronchitis virus, Newcastle disease virus and egg drop syndrome virus.

5. PHARMACEUTICAL DATA

5.1 Major incompatibilities

Do not mix with other veterinary medicinal products.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 12 months.

Shelf life after first opening of the primary packaging: 10 hours.

5.3 Special precautions for storage

Keep and transport refrigerated (between 2°C and 8°C).

Do not freeze

Protect from light.

5.4 Nature and composition of primary packaging

Low-density polyethylene (LDPE) bottle with a volume of 100 and 500 mL, sealed with a rubber stopper and a removable plastic-aluminum cap. Carton containing 1 or 5 bottle(s).

5.5 Special precautions to be taken when disposing of unused veterinary medicinal products or waste derived from the use of such products

Use the take-back arrangements put in place for the disposal of any unused veterinary medicinal product or waste derived therefrom, in accordance with local requirements and any national collection scheme applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

CEVA ANIMAL HEALTH

7. MARKETING AUTHORISATION NUMBER(S)

FR/V/7733777 5/2024

Box of 1 bottle of 100 mL
Box of 1 bottle of 500 mL
Box of 5 bottles of 100 mL
Box of 5 bottles of 500 mL

Not all pack sizes may be marketed.

8. DATE OF FIRST AUTHORIZATION

09/07/2024

9. DATE OF LAST UPDATE TO THE SUMMARY OF PRODUCT FEATURES

26/03/2026

LIMIT MARKETS

EXCEPTIONAL CIRCUMSTANCES

10. CLASSIFICATION OF VETERINARY MEDICINES

Veterinary medicine requiring a prescription.

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