

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cevac Meta L lyophilisate for oculonasal suspension for chickens

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose contains:

Active substance:

Live, attenuated avian metapneumovirus, subtype B, strain CRR126 2.5-3.8 log₁₀ TCID₅₀*

*TCID₅₀ = 50% Tissue culture infective dose: the virus titre required to produce infection in 50% of the tissue culture inoculated.

Excipients:

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Lyophilisate for oculonasal suspension
Yellowish white lyophilisate

4. CLINICAL PARTICULARS

4.1 Target species

Chickens

4.2 Indications for use, specifying the target species

For active immunisation of future layer chickens in order to reduce respiratory signs and virus shedding associated with infection by avian metapneumovirus which is known to be the primary etiological agent of Swollen Head Syndrome.

Onset of immunity: 3 weeks after vaccination.

Duration of immunity: 9 weeks after vaccination.

4.3 Contraindications

None

4.4 Special warnings for each target species

Vaccinate healthy animals only.

4.5 Special precautions for use

Special precautions for use in animals:

Vaccinated chickens may excrete the vaccine strain up to 20 days following vaccination.

The vaccine strain can spread to unvaccinated birds.

In order to reduce the chance of circulation of the vaccine strain, it is recommended to vaccinate all susceptible animals on a site, preferably at the same time

Appropriate veterinary and husbandry measures, such as cleaning and disinfection, should be taken to avoid spread of the vaccine strain to susceptible species.

Unvaccinated birds should be separated from vaccinated chickens.

Turkeys in contact with vaccinated chickens may react to the vaccine strain and show clinical signs such as slight sneezing or conjunctivitis, which may last for 2-3 days.

It is advised not to vaccinate in the presence of other sensitive species (guinea fowl, pheasant and Muscovy ducks), taking into account the spread of the vaccine strain and the lack of safety data for these species.

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

Personal protective equipment consisting of waterproof gloves and safety glasses should be worn when handling the veterinary medicinal product.

The vaccine strain can be found in the environment for up to 4 weeks. Personnel involved in attending vaccinated chickens 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 chickens.

4.6 Adverse reactions (frequency and seriousness)

None.

4.7 Use during pregnancy, lactation or lay

Laying birds:

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

4.8 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.

Simultaneous use of the vaccine with any other vaccine may decrease and/or delay the immune response to either vaccine. 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.

4.9 Amounts to be administered and administration route

For oculonasal use

One dose of the vaccine should be administered by eye-drop from 1 day of age or by coarse spray from 5 weeks of age.

Eye-drop application:

The vaccine should be dissolved in distilled water or alternatively in cool, clean chlorine free water. The appropriate number of vials should be opened and reconstituted. 30 ml of water can be calculated for each 1000 dose of vaccine.

Hold the chicken to be vaccinated with the head tilted to one side. Administer one drop (around 0.03 ml) of dissolved vaccine onto the eye of the bird.

Spraying:

The vaccine should be dissolved in distilled water or alternatively in cool, clean chlorine free water. The appropriate number of vials should be opened and reconstituted. The volume of water for reconstitution should be sufficient to ensure an even distribution when sprayed onto the chickens. This will vary according to the age of the chickens being vaccinated and the management system, but 400-500 ml of water can be calculated for each 1000 dose. The vaccine suspension should be spread evenly over the appropriate number of chickens, at a distance of 30-40 cm. Vaccination is recommended in the form of coarse spray assuring a droplet size of 100-150 µm. The spray apparatus should be free from sediments and corrosion traces or disinfectants. For effective vaccine distribution, make sure that birds are closely confined together, preferably in dimmed light, during spraying.

Depending on housing conditions ventilation should be switched off during and after vaccination in order to avoid turbulences.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

Ten-fold overdose application of the vaccine strain was shown to be safe for future layers.

4.11 Withdrawal period(s)

Zero days

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Immunologicals for aves, domestic fowl, live viral vaccines

ATC vet code: QI01AD01

To stimulate active immunity against avian metapneumovirus.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sucrose

Lactose

Sorbitol
Potassium dihydrogen phosphate
Dipotassium phosphate
Gelatine
Water for injections

6.2 Major incompatibilities

Do not mix with any other veterinary medicinal product.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after reconstitution according to directions: 2 hours.

6.4 Special precautions for storage

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

6.5 Nature and composition of immediate packaging

Clear, hydrolytic, type I glass vials closed with bromobutyl rubber stoppers, and sealed with aluminium caps with a plastic tear-off disc, in a cardboard box.

One vial contains 500, 1000, 2000, 2500, 3000, 4000 or 5000 doses.

Pack sizes:

Cardboard box with 1, 10 or 20 vials of 500 doses of vaccine.
Cardboard box with 1, 10 or 20 vials of 1000 doses of vaccine.
Cardboard box with 1, 10 or 20 vials of 2000 doses of vaccine.
Cardboard box with 1, 10 or 20 vials of 2500 doses of vaccine.
Cardboard box with 1, 10 or 20 vials of 3000 doses of vaccine.
Cardboard box with 1, 10 or 20 vials of 4000 doses of vaccine.
Cardboard box with 1, 10 or 20 vials of 5000 doses of vaccine.

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Ceva Animal Health Ltd
Explorer House
Mercury Park
Wycombe Lane
Wooburn Green
High Wycombe
Buckinghamshire
HP10 0HH
United Kingdom

8. MARKETING AUTHORISATION NUMBER

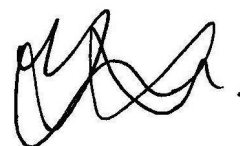
Vm 15052/4086

9. DATE OF FIRST AUTHORISATION

10 October 2016

10. DATE OF REVISION OF THE TEXT

September 2022

A handwritten signature in black ink, consisting of several loops and a final horizontal stroke.

Approved: 23 September 2022