LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box with 1 x ,10 x or 20 x 500, 1000, 2000, 2500, 3000, 4000 and 5000 doses

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cevac Meta L lyophilisate for oculonasal suspension for chickens

2. STATEMENT OF ACTIVE SUBSTANCES

Each dose contains:
Live, attenuated avian metapneumovirus subtype B, strain CRR126 2.5 - 3.8 log10 $TCID_{50}$

3. PHARMACEUTICAL FORM

Lyophilisate for oculonasal suspension

4. PACKAGE SIZE

1 x 500 doses
1 x 1000 doses
1 x 2000 doses
1 x 2500 doses
1 x 3000 doses
1 x 4000 doses
1 x 5000 doses

10 x 500 doses
10 x 1000 doses
10 x 2000 doses
10 x 2500 doses
10 x 3000 doses
10 x 4000 doses
10 x 5000 doses

20 x 500 doses
20 x 1000 doses
20 x 2000 doses
20 x 2500 doses
20 x 3000 doses
20 x 4000 doses
20 x 5000 doses

5. TARGET SPECIES

Chickens

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For oculonasal use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD (S)

Withdrawal period: zero days

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Once reconstituted use within 2 hours.

11. SPECIAL STORAGE CONDITIONS

Store and transport refrigerated.
Do not freeze.
Protect from light.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only. <To be supplied only on veterinary prescription.>
{To be completed nationally}

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

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Ceva Animal Health Ltd
Unit 3, Anglo Office Park
White Lion Road
Amersham
Buckinghamshire
HP7 9FB

16. MARKETING AUTHORISATION NUMBER(S)

Vm 15052/4086

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Vials of 500, 1000, 2000, 2500, 3000, 4000 and 5000 doses

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cevac Meta L lyophilisate for oculonasal suspension for chickens

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

aMPV subtype B, 2.5-3.8 log10 $TCID_{50}$/dose

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

500 doses
1000 doses
2000 doses
2500 doses
3000 doses
4000 doses
5000 doses

4. ROUTE(S) OF ADMINISTRATION

For oculonasal use

5. WITHDRAWAL PERIOD(S)

Withdrawal period: zero days

6. BATCH NUMBER

Lot: {number}

7. EXPIRY DATE

EXP {month/year}
Once reconstituted use within 2 hours.

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
Cevac Meta L lyophilisate for oculonasal suspension for chickens

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder and manufacturer responsible for batch release:

Marketing authorisation holder:
Ceva Animal Health Ltd
Unit 3, Anglo Office Park
White Lion Road
Amersham
Buckinghamshire
HP7 9FB

<Manufacturer responsible for batch release>
Ceva-Phylaxia Co. Ltd.
1107 Budapest, Szállás u. 5.
Hungary

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cevac Meta L lyophilisate for oculonasal suspension for chickens

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Each dose contains:
Active substance:
Live, attenuated avian metapneumovirus subtype B, strain CRR126 2.5-3.8 log10 $TCID_{50}$*
*$TCID_{50}$ = 50% Tissue culture infective dose: the virus titre required to produce infection in 50% of the tissue culture inoculated.

Yellowish white lyophilisate.

4. INDICATION(S)

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.

5. CONTRAINDICATIONS

None

6. ADVERSE REACTIONS

None

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 inform your veterinary surgeon.

7. TARGET SPECIES

Chickens

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

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.

9. ADVICE ON CORRECT ADMINISTRATION

Eye-drop application:
The vaccine should be dissolved in distilled water for or alternatively in cool, clean chlorine free water. The appropriate number of vials should be opened and reconstituted. 30 ml of diluent 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 of 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.

10. WITHDRAWAL PERIOD(S)

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 label after EXP. The expiry date refers to the last day of that month.

Shelf life after reconstitution according to directions: 2 hours

12. SPECIAL WARNING(S)

Special warnings for each target species:
Vaccinate healthy animals only.

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.

Lay:
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.
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.

Overdose (symptoms, emergency procedures, antidotes):
Ten-fold overdose application of the vaccine strain was shown to be safe for future layers.

Incompatibilities:
Do not mix with any other medicinal product.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

September 2021

15. OTHER INFORMATION

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

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.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

Approved: 01/12/21