ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Package label: 1x, 10 x or 20 x 1000/2500/5000 doses

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

CEVAC MASS L lyophilisate for oculonasal suspension for chickens

2. STATEMENT OF ACTIVE SUBSTANCES

Each dose (0.2 ml) contains: Infectious bronchitis virus, Massachusetts B-48 strain $10^{2.8}$ - $10^{4.3}$ EID_{50}

3. PHARMACEUTICAL FORM

Lyophilisate for oculonasal suspension

4. PACKAGE SIZE

1 x 1000 doses
1 x 2500 doses
1 x 5000 doses
10 x 1000 doses
10 x 2500 doses
10 x 5000 doses
20 x 1000 doses
20 x 2500 doses
20 x 5000 doses

5. TARGET SPECIES

Chickens

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Nebulisation use.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period: zero days.

9. SPECIAL WARNING(S), IF NECESSARY

Read package leaflet before use and disposal.

10. EXPIRY DATE

EXP:
Once reconstituted, use within 2 hours.

11. SPECIAL STORAGE CONDITIONS

Store and transport refrigerated.
Protect from light.

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

Read package leaflet before use and disposal.

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.

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
Explorer House
Mercury Park
Wycombe Lane
Wooburn Green
High Wycombe
Buckinghamshire
HP10 0HH
United Kingdom

16. MARKETING AUTHORISATION NUMBER(S)

Vm 15052/4088

17. MANUFACTURER'S BATCH NUMBER

Lot:

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Glass vial label – 1000, 2500, 5000 doses

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

CEVAC MASS L lyophilisate for oculonasal suspension

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Infectious bronchitis virus, Massachusetts B-48 strainmin. $10^{2.8}$ EID_{50} per dose

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

1000 doses
2500 doses
5000 doses

4. ROUTE(S) OF ADMINISTRATION

Nebulisation use.

5. WITHDRAWAL PERIOD(S)

Withdrawal period: zero days.

6. BATCH NUMBER

Lot:

7. EXPIRY DATE

EXP:

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
CEVAC MASS 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:
Ceva Animal Health Ltd
Explorer House
Mercury Park
Wycombe Lane
Wooburn Green
High Wycombe
Buckinghamshire
HP10 0HH
United Kingdom

Manufacturer responsible for batch release:
CEVA-Phylaxia Co. Ltd.
1107 Budapest
Szállás u 5.
Hungary

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

CEVAC MASS L lyophilisate for oculonasal suspension for chickens

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

Each dose (0.2 ml) contains:
Active substance:
Live, attenuated infectious bronchitis virus (IBV), Massachusetts B-48 strain $10^{2.8}$ - $10^{4.3}$ EID_{50}*
*EID_{50} = 50% embryo infective dose

Yellowish pellet.

4. INDICATION(S)

For the active immunisation of broilers and future layers against infectious bronchitis (Massachusetts serotype), in order to reduce respiratory clinical signs, detrimental effect on the ciliary activity and presence of virus in the trachea.
Protection was demonstrated by challenge with the Massachusetts M41 strain.

Onset of immunity: 3 weeks following vaccination.
Duration of immunity: 9 weeks following vaccination.

5. CONTRAINDICATIONS

None.

6. ADVERSE REACTIONS

No significant clinical symptoms were detected after administration of the product. Mild tracheal rales commonly occurred in animals 4-6 days after vaccination, which resolved completely in a few days. In rare cases transient conjunctivitis can occur.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports)

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 nebulisation use.
The vaccine should be administered from one day of age, one dose / chicken.

9. ADVICE ON CORRECT ADMINISTRATION

Reconstitute the vaccine in distilled water, or in cold, clear water free from disinfectants. The quantity of water should be sufficient to allow a uniform distribution of the vaccine when spraying the chickens. The content of a 1000-dose vaccine vial is recommended to be dissolved in 200 ml water, whereas this ratio should be considered when dissolving other types of presentation.
The vaccine should be applied as coarse spray with a droplet size of 100-200 µm. It is preferable that the chickens are sitting together in dim light or closely confined during spraying. The ventilation should be switched off during and after vaccination in order to avoid turbulences.
Vaccination should be performed during the coolest time of the day.

10. WITHDRAWAL PERIOD(S)

Zero days.

11. SPECIAL STORAGE PRECAUTIONS

Store and transport refrigerated (2 °C - 8 °C).
Protect from light.
Shelf life after reconstitution according to directions: 2 hours
The reconstituted vaccine is to be kept below 25°C.
Do not use this veterinary medicinal product after the expiry date which is stated on the label (EXP).
Keep out of the sight and reach of children.

12. SPECIAL WARNING(S)

Special precautions for use in animals:
Vaccinate healthy animals only.
Vaccinated chickens may excrete the vaccine strain for up to 28 days following vaccination. During this time, special precautions should be taken to avoid spreading of the vaccine strain to unvaccinated chickens and to other bird species, if any are close by.
All chickens within the same farm should be vaccinated before or when entering the premises.

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

Care should be taken when reconstituting and administering the vaccine. Wash and disinfect hands and equipment after administration of the vaccine. When spraying the vaccine, personal protective equipment consisting of a mask with eye protection should be worn by the operator and staff.

Lay:
The safety of the veterinary medicinal product has not been studied during lay.
Do not use in birds in lay and within 4 weeks before the onset of the laying period.

Interaction with other medicinal products and other forms of interaction:
Safety and efficacy data are available which demonstrate that this vaccine can be mixed and administered with Cevac IBird by spray application in chickens from day old onwards. Do not use the mixed products in birds in lay and within 4 weeks before the onset start of the laying period. The mixed products protect against strains belonging to Massachusetts and 793/B groups of IBV. The safety parameters of the mixed vaccines are not different from those described for the vaccines administered separately. Read the product information of Cevac IBird before use.
Care should be taken to avoid spreading of the vaccine strains to other bird species, in particular when the vaccines are mixed.
Simultaneous use of both vaccines may increase the risk of recombination of viruses and potential emergence of new variants. However, the chance of a hazard occurring has been estimated very low.

No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product except Cevac IBird. 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)**:**
No further reactions above the side effects mentioned under adverse reactions were observed after administering a 10-fold dose of the vaccine.

Incompatibilities:
Do not mix with any other veterinary medicinal product except with Cevac IBird (where it is marketed).

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

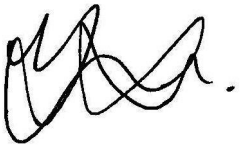
October 2022

15. OTHER INFORMATION

1000, 2500 or 5000 doses in glass vials.
1, 10 or 20 vials in a cardboard box.

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: 04 October 2022