Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

CEVAC MASS L lyophilisate for oculonasal suspension for chickens

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

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

Excipients

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Lyophilisate for oculonasal suspension.
Yellowish pellet.

4 CLINICAL PARTICULARS

4.1 Target Species

Chickens (broilers and future layers)

4.2 Indications for use, specifying the target species

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.

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 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.

4.6 Adverse reactions (frequency and seriousness)

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)

4.7 Use during pregnancy, lactation or lay

Laying birds:
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 start of the laying period.

4.8 Interaction with other medicinal products and other forms of interactions

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.

4.9 Amounts to be administered and administration route

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

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

No further reactions above the side effects mentioned under adverse reactions were observed after administering a 10-fold dose of the vaccine.

4.11 Withdrawal period(s)

Zero days.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: immunologicals for aves / domestic fowl / live viral vaccines / avian infectious bronchitis virus
ATCvet code: QI01AD07

To stimulate active immunity against the Massachusetts serotype of avian infectious bronchitis virus in chickens.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sucrose
Lactose
Sorbitol
Gelatine
Potassium dihydrogen phosphate
Dipotassium phosphate

6.2 Major incompatibilities

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

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).
Protect from light.
The reconstituted vaccine is to be kept below 25°C.

6.5 Nature and composition of immediate packaging

The vaccine is supplied in 3 or 10 ml type I glass vials, sealed with bromobutyl rubber stoppers and aluminium caps with plastic (flip-off) tops.

Pack sizes:
Cardboard box with 1 vial of 1000 doses
Cardboard box with 1 vial of 2500 doses
Cardboard box with 1 vial of 5000 doses
Cardboard box with 10 vials of 1000 doses
Cardboard box with 10 vials of 2500 doses
Cardboard box with 10 vials of 5000 doses
Cardboard box with 20 vials of 1000 doses
Cardboard box with 20 vials of 2500 doses
Cardboard box with 20 vials of 5000 doses

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal products 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-Phylaxia Veterinary Biologicals Co. Ltd
1107 Budapest
Szállás u. 5.
Hungary

8 MARKETING AUTHORISATION NUMBER(S)

VPA10463/004/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 20 May 2016
Date of last renewal: 05 February 2021

10 DATE OF REVISION OF THE TEXT

February 2021