1. NAME OF THE VETERINARY MEDICINAL PRODUCT

CEVAC MASS L lyophilisate for oculonasal suspension

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 0.2 ml dose contains:

Active substances:

Avian infectious bronchitis virus (IBV), type Massachusetts, strain B-48, Live, attenuated
$10^{2.8}$ - $10^{4.3}$ EID_{50}*
*EID_{50}= 50% embryo infective dose

Excipients:

Qualitative composition of excipients and other constituents
Sucrose
Lactose
Sorbitol
Gelatin
Potassium dihydrogen phosphate
Dipotassium phosphate

Yellowish pellet.

3. CLINICAL INFORMATION

3.1 Target species

Chickens (broilers and future layers)

3.2 Indications for use for each 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.

3.3 Contraindications

None.

3.4 Special warnings

Vaccinate healthy animals only.

3.5 Special precautions for use

Special precautions for safe use in the target species:
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. Personal protective equipment consisting of a mask with eye protection should be worn when handling the veterinary medicinal product. Wash and disinfect hands and equipment after administration of the vaccine.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Chicken:

Common (1 to 10 animals / 100 animals treated):	Tracheal rales[1]
Rare (1 to 10 animals / 10 000 animals treated):	Conjunctivitis[2]

[1] 4-6 days after vaccination, resolving completely in a few days.
[2]Transient

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Laying birds:

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

3.8 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. 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.

3.9 Administration routes and dosage

Oculonasal 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.
The reconstituted product is a clear, colourless liquid.

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

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

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Zero days.

4. IMMUNOLOGICAL INFORMATION

4.1 ATCvet code: QI01AD07

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

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

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

5.2 Shelf life

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

5.3 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.

5.4 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.

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

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

CEVAC MASS L lyophilisate for oculonasal suspension

7. MARKETING AUTHORISATION NUMBER(S)

VPA10463/004/001

8. DATE OF FIRST AUTHORISATION

20/05/2016

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

10/07/2026

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

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