SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

CEVAC IBird lyophilisate for oculonasal suspension/ use in drinking water for chickens

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose contains:

Active substance:
Live, attenuated infectious bronchitis (IB) virus, strain 1/96, 2.8 – 4.3 log10 EID50*

*EID50 = 50 % Embryo infective dose: the virus titre required to produce infection in 50% of the embryos inoculated.

Excipients:

Qualitative composition of excipients and other constituents
Gelatine
• Lactose
• Sorbitol
Sucrose
Potassium dihydrogen phosphate
Dipotassium hydrogen phosphate
• Water for injections

Appearance: Yellowish white pellet

3. CLINICAL INFORMATION

3.1 Target species

Chickens

3.2 Indications for use for each target species

For the active immunisation of broiler and future layer chickens in order to reduce the detrimental effect on the ciliary activity and presence of virus in trachea resulting from the infection, which may be manifested in respiratory clinical signs. Protection was demonstrated by challenge with the 793/B strain, which is a representative strain of the 793/B group.

Onset of immunity: 3 weeks after one vaccination.

Duration of immunity: 6 weeks after one vaccination, except for future layers in which duration of immunity is 9 weeks after the first vaccination by spraying.

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:

All chickens on a site should be vaccinated at the same time and within the same premises.
The vaccine strain may spread to non-vaccinated chickens. Vaccinated chickens may excrete the vaccine strain for up to 28 days or longer following vaccination. During this time, the contact of immunosuppressed and unvaccinated chickens with vaccinated chickens should be avoided.
Care should be taken to avoid spread of the vaccine virus from vaccinated chickens to pheasants and turkeys.
Cevac IBird is intended to protect chickens against respiratory disease caused by variant strains of infectious bronchitis virus belonging to the 793/B group and should not be used as a replacement for other IBV vaccines.
The veterinary medicinal product should not be used without a diagnosis being made that infection is caused by a strain of the 793/B group and after it has been established that the IB virus group 793/B is epidemiologically relevant in this area. Care should be taken to avoid the introduction of the variant group into an area where it is not present.

Good animal husbandry, hygiene practices (e.g. cleaning and disinfection procedures, changing clothing and shoes for visitors) can effectively help to protect the environment.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
The vials should be opened under water to avoid aerosol forming.
Personal protective equipment consisting of waterproof gloves and safety glasses should be worn when handling the veterinary medicinal product. Wash hands after using this product.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Common (1 to 10 animals / 100 animals treated):	Tracheal rales*

* Slight tracheal rales were observed after vaccination with the product which may persist for at least 10 days.

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 the national competent authority via the national reporting system. See section “Contact details” of the package leaflet.

3.7 Use during pregnancy, lactation or lay

Laying birds: the repeated use of Cevac IBird has been shown to be safe in layers during lay.

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 Mass L by spray application in chickens from 1 day of age onwards.
After mixed administration with Cevac Mass L the duration of immunity in broiler chicken was shown to be 9 weeks.
No information is available on the safety and efficacy of Cevac IBird when mixed and administered with Cevac Mass L to hens during laying period.
The mixed products protect against strains belonging to 793/B and Massachusetts 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 Mass L 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 Mass L. 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 for broiler and future layer chickens
One dose of the vaccine should be administered by spraying from 1 day of age. Older chickens can also be vaccinated by spraying.
The vaccine should preferably be dissolved in distilled water or alternatively in cool, clean chlorine free water. The appropriate number of vials should be opened under water. 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 at least 200 ml of water per 1000 doses is suggested. The vaccine suspension should be spread evenly over the correct number of chickens, at a distance of 30-40 cm using droplet sizes in a range of 100-200 µm (coarse spray). Spraying is preferable when the chickens are sitting together in dim light. 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 during spraying.

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

In drinking water use for future layer chickens
One dose of the vaccine should be administered by drinking water from 10 days of age. In order to maintain immunity, chickens may be revaccinated every 3 weeks. No studies were done to show protection during the laying period.
The vaccine should be dissolved in the drinking water. The amount of water should be calculated based on the average water consumption of the flock in the previous 4 days before vaccination. Calculate the amount of water needed, so that the vaccine is consumed within 2 hours. This amount should be approximately 30% of the daily intake.
Medication, disinfectants and chlorine must be removed from the drinking water 48 hours before vaccination.
Water should be withheld prior to vaccination to make the chickens thirsty. The period for water withdrawal is dependent on the climate. Water withholding should be kept as short as possible with a minimum of 30 minutes.
The vials should be opened under water. Use cool, clean water to dissolve the vaccine. For administration of the vaccine, as a general rule, dissolve 1000 doses in one litre per age in days up to a maximum volume of 20 litres per 1000 doses, or in hot weather, the quantity of water may be increased up to 40 litres per 1000 doses.

Appearance of the reconstituted product: From slightly opalescent to colourless liquid.

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

No side effects other than those listed in paragraph “Adverse events” have been observed following the administration of ten times the recommended dose of 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 in chickens against avian infectious bronchitis virus, strain 1/96 belonging to the 793/B virus group.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product, except Cevac Mass L where it is marketed.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 18 months
Shelf life after reconstitution according to directions: 2 hours

5.3 Special precautions for storage

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

5.4 Nature and composition of immediate packaging

The vaccine is supplied in 3 and 10 ml clear glass vials of hydrolytic glass type I. The vial is closed with bromobutyl stoppers, and sealed with aluminium caps with plastic tear-off centres.
1 vial contains 500, 1000, 2500, 5000 or 10000 doses presented in a cardboard box with 1, 10 or 20 vials/ box.

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

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

7. MARKETING AUTHORISATION NUMBER

Vm 15052/3011

8. DATE OF FIRST AUTHORISATION

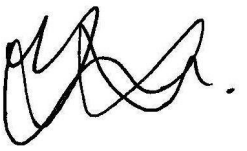
16 August 2013

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

June 2023

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).



Approved: 30 June 2023