

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

**BOX (1,000, 2,500 or 5,000 doses, 20 vials per box)**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Cevac IBD 2512 L lyophilisate for oral suspension for chickens

**2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES**

Live avian infectious bursal disease virus, strain Winterfield 2512, G-61 2.0 log<sub>10</sub> to 3.2 log<sub>10</sub> EID<sub>50</sub>\*/dose

\* EID<sub>50</sub> – embryo infectious dose 50%

**3. PHARMACEUTICAL FORM**

Lyophilisate for oral suspension.

**4. PACKAGE SIZE**

20 x 1,000 doses

20 x 2,500 doses

20 x 5,000 doses

**5. TARGET SPECIES**

Chickens

**6. INDICATION(S)**

**7. METHOD AND ROUTE OF ADMINISTRATION**

In drinking water use.

Read the package leaflet before use.

**8. WITHDRAWAL PERIOD**

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. SPECIAL 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.

**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 15052/4059

<b>17. MANUFACTURER'S BATCH NUMBER</b>
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Lot: {number}

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS**

**VIAL** (1,000, 2,500, 5,000 doses)

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Cevac IBD 2512 L lyophilisate for oral suspension for chickens

**2. QUANTITY OF THE ACTIVE SUBSTANCE**

Live IBD virus, Winterfield 2512, G-61 strain, 2.0 log<sub>10</sub> to 3.2 log<sub>10</sub> EID<sub>50</sub>/dose

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

1,000 doses

2,500 doses

5,000 doses

**4. ROUTE(S) OF ADMINISTRATION**

In drinking water use.

**5. WITHDRAWAL PERIOD**

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.

**PACKAGE LEAFLET FOR:**  
**Cevac IBD 2512 L lyophilisate for oral 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 the batch release:

Ceva-Phylaxia Zrt., Szállás u. 5, 1107 Budapest, HUNGARY.

**2. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Cevac IBD 2512 L lyophilisate for oral suspension for chickens

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

One dose contains:

**Active substance:**

Live avian infectious bursal disease (IBD) virus, strain Winterfield 2512, G-612.0 log<sub>10</sub> to 3.2 log<sub>10</sub> EID<sub>50</sub>\*/dose

\* EID<sub>50</sub> – embryo infectious dose 50%.

Lyophilisate for oral suspension.

Blue freeze-dried powder.

**4. INDICATION(S)**

For the active immunization of broiler chickens from 10 days of age with maternally derived antibodies against avian infectious bursal disease (IBD, Gumboro disease), to reduce mortality, clinical symptoms, weight loss and acute lesions in bursa of Fabricius, caused by very virulent infectious bursal disease virus.

Onset of immunity: 14 days post-vaccination.

Duration of immunity: 27 days post-vaccination.

## 5. CONTRAINDICATIONS

Do not use in infected flocks with clinical symptoms.

Do not use for immunisation of flocks without maternally derived antibodies (MDA). (See “Special precautions for use in animals”)

## 6. ADVERSE REACTIONS

Data from safety studies involving administration of a single dose to the target species (10 day old chickens with MDA to IBD virus) are not available.

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

## 7. TARGET SPECIES

Chickens (broilers)

## 8. DOSAGE FOR EACH SPECIES, ROUTE AND METHOD OF ADMINISTRATION

In drinking water use.

Dosage: 1 dose / chicken.

For oral administration, via reconstitution in drinking water.

## 9. ADVICE ON CORRECT ADMINISTRATION

For vaccination of broiler chickens from a minimum of 10 days of age to approximately 18 days of age, depending on the level of maternally derived antibodies.

The optimal timing of vaccination should be determined on the basis of virus neutralisation (VN) titres measured in 1- to 7-day-old chickens. The flock to be vaccinated should have a geometric mean VN titre of  $\leq 1:450$  at vaccination.

To estimate MDA level of the flock to be vaccinated: 20, preferably 1-day-old chicks (maximum 7 day old) originating from the same breeding flock should be sampled to measure their serological status to IBD virus by VN. From the results of this sampling and based on the 3 days half-life-time for the IBD virus MDA, the most suitable time for vaccination can be determined.

### Preparation and administration of the vaccine:

The number of vaccine doses should be dissolved in the amount of drinking water calculated upon water consumption of the birds to be immunized.

Age	10–12 days	14–18 days
minimal amount of water for 1000 vaccine doses (for treatment of 1000 birds)	10 litres	15 litres

Number of doses should be rounded up for smaller flocks and dissolved accordingly (i.e. dissolve 20,000 doses for the treatment of 19,450 birds).

Drinking water must not contain disinfectants for 48 hours prior to and for 24 hours after vaccination. Also chlorination of drinking water should be avoided during this period. Instruments used for preparation and administration of the vaccine must be free of residues of disinfectants.

Drinkers should be cleaned thoroughly before vaccination. Do not apply disinfectants for cleaning of the watering system for vaccination.

Drinking water should be withdrawn from birds for 2 to 4 hours prior to vaccination, depending on their age and the temperature of the house.

To preserve virus activity, it is advised to dissolve 2.5 g skimmed milk powder per litre of calculated drinking water, prior to dissolving the vaccine.

Open the vaccine vial under water and rinse it thoroughly after dissolution. Stir to dissolve the vaccine, distribute it to watering system proportionally and make it available to the chickens. It is advised to increase the number of drinkers during vaccination. To ensure that all birds have access to the vaccinated water, it is advised to move birds around the drinkers in the first few minutes of vaccination. The birds can be supplied with fresh drinking water only after the medicated water is consumed entirely.

The vaccine should be administered to birds immediately after reconstitution.

Administer the vaccine during the coolest part of the day.

Protect reconstituted vaccine from direct sunshine.

Protect birds to be vaccinated from stress conditions.

## **10. WITHDRAWAL PERIOD**

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 veterinary medicinal product after the expiry date (EXP) which is stated on the label.

Shelf life after reconstitution according to directions: 2 hours.

## **12. SPECIAL WARNINGS**

Special warnings for each target species:

The vaccine contains an “intermediate-plus” virus strain that is known to cause immunosuppression and bursal damage in specific circumstances (see “Special precautions for use in animals”). Consequently, the vaccine is only indicated for immunisation of chicken having maternal antibodies and exposed to very virulent IBD virus strains.

Special precautions for use in animals.

Vaccinate healthy birds only. It is not recommended to vaccinate birds younger than 10

days of age, regardless of the level of maternally derived antibodies (see “Advice on correct administration”). The vaccine contains an “intermediate-plus” virus strain, causing significant immunosuppression and bursal damage when inoculated into birds without MDA. Vaccinated birds may excrete the vaccine virus that may subsequently spread to susceptible birds. To prevent spread of vaccine virus, vaccinating equipment and chicken houses should be disinfected between flocks. The product should be only used after it has been demonstrated that very virulent IBDV strains are epidemiologically relevant in the area of vaccination. Vaccinate all the birds in a flock at the same time.

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

Personnel performing vaccination should wash and disinfect hands and equipment after use.

Lay:

Do not use in layers or breeders.

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. 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):

From studies involving a 10 fold overdose of Winterfield 2512 L G61 vaccine strain administered to 1-day-old and 7-day-old chickens without maternally derived antibodies (i.e. SPF chickens) the following was noted:

In 1-day-old SPF chickens: lesions of 2.2 scores in the bursa of Fabricius were observed by 28 days post-vaccination as well as a slower growth rate up to three weeks of age.

In 7-day-old SPF chickens: clinical signs of infectious bursal disease were not detected. No oedema, haemorrhage or necrosis was detected in the bursa of any chicken by the end of the 21-day observation period.

Incompatibilities:

Chlorides and metal ions in the drinking water may interfere with the vaccine virus.

Residues of disinfectants on the surface of instruments to be used for preparation and administration of the vaccine may interfere with the live virus and may reduce vaccine efficacy.

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

Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.



#### **14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED**

October 2022

#### **15. OTHER INFORMATION**

ATCvet code: QI01AD09.

Pharmacotherapeutic group: immunologicals for Aves, domestic fowl, live viral vaccines, avian infectious bursal disease virus (Gumboro disease).

Lyophilised vaccine: 1,000, 2,500 and 5,000 doses in type I glass vials of 3 ml and 10 ml volume, sealed with rubber stopper and aluminium cap.

20 vials in a box.

Not all pack sizes may be marketed.

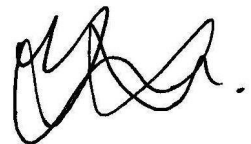
For animal treatment only. To be supplied only on veterinary prescription.

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

To be distributed by companies authorised for distribution of veterinary medicinal products.

The manufacture, import, possession, sale, supply and/or use of Cevac IBD 2512 L may be prohibited in a Member State on the whole or part of their territory pursuant to national legislation. Any person intending to manufacture, import, possess, sell, supply and/or use Cevac IBD 2512 L must consult the relevant Member State's competent authority on the current vaccination policies prior to the manufacture, import, possess, sale, supply and/or use.

Marketing authorisation number(s)  
Vm 15052/4059



Approved: 05 October 2022