1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cevac IBD 2512 L lyophilisate for use in drinking water

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose contains:

Active substances:
Infectious bursal disease virus, strain Winterfield 2512, (G-61, intermediate plus), Live
2.0 log10 to 3.2 log10 EID50*
* EID50 embryo infectious dose 50%

Excipients:

Qualitative composition of excipients and other constituents
Lactalbumin hydrolysate
Sucrose
Sodium-L-glutamate
Potassium dihydrogen phosphate
Dipotassium phosphate
Patent blue (E131)

Blue lyophilisate.

3. CLINICAL INFORMATION

3.1 Target species

Chickens (broilers).

3.2 Indications for use for each target species

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.

3.3 Contraindications

Do not use in infected flocks with clinical symptoms.
Do not use for immunisation of flocks without maternally derived antibodies (MDA). See section 3.5.

3.4 Special warnings

Vaccinate healthy animals only.

3.5 Special precautions for use

Special precautions for safe use in the target species:

It is not recommended to vaccinate birds younger than 10 days of age, regardless of the level of maternally derived antibodies (see section 3.9).
The vaccine contains an "intermediate-plus" virus strain, that is known to cause significant immunosuppression and bursal damage when inoculated into birds without MDA. Consequently, the vaccine is only indicated for immunisation of chicken having maternal antibodies and exposed to very virulent IBD virus strains. 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.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Target species: Chicken

None known.

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:
Do not use in birds in lay or breeding birds.

3.8 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.

3.9 Administration routes and dosage

In drinking water use.
Dosage: 1 dose / chicken.
For oral administration, via reconstitution in drinking water.
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-lifetime 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 1,000 vaccine doses (for treatment of 1,000 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. When the colour of the water homogeneously changes (blue dye), 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.

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

From studies involving a 10-fold overdose of the vaccine strain Winterfield 2512 (G-61, intermediate plus) 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.

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:

QI01AD09
For active immunisation against avian infectious bursal disease virus (Gumboro disease, IBD).
The vaccine contains live, attenuated IBD virus.

5. PHARMACEUTICAL PARTICULARS

5.1 Major 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.

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).
Do not freeze.
Protect from light.

5.4 Nature and composition of immediate packaging

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.

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 Santé Animale

7. MARKETING AUTHORISATION NUMBER(S)

VPA10815/020/001

8. DATE OF FIRST AUTHORISATION

14/12/2012

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

18/09/2026

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).