

*[Version 8, 10/2012]*

*ibd-2512-l-pi-2016-08-20-en-clean*

## **ANNEX I**

### **SUMMARY OF PRODUCT CHARACTERISTICS**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cevac IBD 2512 L lyophilisate for oral suspension for chickens

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One dose contains:

### Active substance:

Live avian infectious bursal disease (IBD) 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%

### Excipients:

For the full list of excipients, see section 6.1.

## 3. PHARMACEUTICAL FORM

Lyophilisate for oral suspension.

Blue freeze-dried powder.

## 4. CLINICAL PARTICULARS

### 4.1 Target species

Chicken (broilers).

### 4.2 Indications for use, specifying the 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.

### 4.3 Contraindications

Do not use in infected flocks with clinical symptoms.

Do not use for immunisation of flocks without maternally derived antibodies (MDA). (See section 4.5.).

### 4.4 Special warnings for each target species

The vaccine contains an “intermediate-plus” virus strain that is known to cause immunosuppression and bursal damage when inoculated into birds without MDA (see sections 4.5, 4.6 and 5.).

Consequently, the vaccine is only indicated for immunisation of chicken having maternal antibodies and exposed to very virulent IBD virus strains.

### 4.5 Special precautions for use

#### 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 section 4.9).

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.

#### **4.6 Adverse reactions (frequency and seriousness)**

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. Refer to section 4.10.

#### **4.7 Use during pregnancy, lactation or lay**

Do not use in layers or breeders.

#### **4.8 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.

#### **4.9 Amounts to be administered and administration route**

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-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.

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

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.

#### **4.11 Withdrawal period**

Zero days.

### **5. IMMUNOLOGICAL PROPERTIES**

Pharmacotherapeutic group: immunologicals for Aves, domestic fowl, live viral vaccines, avian infectious bursal disease virus (Gumboro disease). ATCvet code: QI01AD09.

For active immunisation against avian infectious bursal disease virus (Gumboro disease, IBD). The vaccine contains live, attenuated, intermediate plus, Winterfield 2512, G61 strain of IBD virus.

### **6. PHARMACEUTICAL PARTICULARS**

#### **6.1 List of excipients**

Lactalbumin hydrolysate  
Sucrose  
Sodium-L-glutamate  
Potassium dihydrogen phosphate  
Dipotassium phosphate  
Patent blue (E131)

#### **6.2 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.

#### **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). Do not freeze.  
Protect from light.

#### **6.5 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.

#### **6.6 Special precautions for the disposal of unused veterinary medicinal product 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**

### **8. MARKETING AUTHORISATION NUMBER(S)**

### **9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

### **10 DATE OF REVISION OF THE TEXT**

#### **PROHIBITION OF SALE, SUPPLY AND/OR USE**

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.