## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nextmune concentrate and solvent for suspension for injection for chickens

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose (0.05 ml *in ovo* or 0.2 ml subcutaneous) contains:

**Active substance:**

Infectious bursal disease virus, serotype 1, strain Winterfield 2512 (intermediate plus), live attenuated
0.7 – 2.7 log10 $CID_{50}$*

* Chicken Infective Dose 50%

**Excipients:**

| **Qualitative composition of excipients and other constituents** | **Quantitative composition if that information is essential for proper administration of the veterinary medicinal product** |
|---|---|
| Vaccine: | |
| BDA (bursal disease antibody) | 1.5 – 2.04 log10 AB unit** |
| sucrose | |
| water for injection | |
| Solvent (Cevac Solvent Poultry): | |
| sucrose | |
| casein hydrolysate | |
| sorbitol | |
| dipotassium hydrogen phosphate | |
| potassium dihydrogen phosphate | |
| phenol red | |
| water for injection | |

** Antibody unit

Vaccine: reddish-brownish frozen suspension.
Solvent: clear, orange to red liquid.

## 3. CLINICAL INFORMATION

### 3.1 Target species

Chickens (broiler and embryonated eggs).

### 3.2 Indications for use for each target species

For active immunisation of 18-day-old broiler embryos or day-old broiler chickens in order to reduce clinical signs, virus shedding and acute lesions of the bursa of Fabricius caused by very virulent avian infectious bursal disease (IBD) virus infection.

In laboratory studies, it was observed that the vaccination with Nextmune can reduce weight loss after infection with vvIBDV as observed 10 days after infection.

Onset of immunity: expected from 21 days of age onwards depending on the initial MDA level.

The immunisation is influenced by the natural decline of maternally derived antibodies (MDA), and has been found to occur when MDA have reached appropriate release level.

Laboratory and field trials have been carried out in birds with MDA titres of 2500-7900 ELISA units.

In vaccinated chicks the release of the vaccine virus (vaccine virus take) was observed between 14-35 days of age in clinical trials.

Duration of immunity: up to 7 weeks of age.

### 3.3 Contraindications

Do not use in embryos or chickens from non-vaccinated parent flocks or having no MDA against IBDV.

### 3.4 Special warnings

Vaccinate healthy animals only.
Vaccinate only MDA positive chickens which have at least an average day-old MDA level of 3200 ELISA units.

### 3.5 Special precautions for use

Special precautions for safe use in the target species:

Vaccinated chickens may excrete the vaccine strain up to 21 days following vaccination. During this time, the contact of immunosuppressed and unvaccinated birds with vaccinated chickens should be avoided.

Appropriate veterinary and husbandry measures should be taken to avoid spread of the vaccine strain to susceptible birds. Vaccinate all the birds in a flock at the same time.

This product should only be used after it has been demonstrated that very virulent IBDV strains are epidemiologically relevant in the area of vaccination.

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

Liquid nitrogen containers and vaccine should be handled by properly trained personnel only.

Personal protective equipment consisting of protective gloves, spectacles and boots should be worn when handling the veterinary medicinal product, before withdrawing from liquid nitrogen, during the ampoule thawing and opening operations.

Frozen glass ampoules can explode during sudden temperature changes. Store and use liquid nitrogen only in a dry and well-ventilated place. Inhalation of the liquid nitrogen is dangerous.

Personnel involved in the treatment of vaccinated birds should use hygiene principles and take particular care in handling litter from vaccinated chickens.

Special precautions for the protection of the environment:

Not applicable.

### 3.6 Adverse events

Chickens (broiler and embryonated eggs):

| | |
|---|---|
| Very common<br>(>1 animal / 10 animals treated): | Bursa of Fabricius lymphocyte depletion[1] |

[1] Mild to moderate which is maximal at around 7 days after vaccine take. After further 7 days, this depletion decreases and is followed by lymphocyte repopulation and regeneration of the bursa of Fabricius.

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

Not applicable.

### 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

The vaccine can be administered by *in ovo* or via subcutaneous use.
Use sterile devices and equipment for reconstitution and for administration of the vaccine.
Match the dose size of the vaccine and the sterile solvent according to the tables below.

<u>*In ovo* administration</u>
One single dose of 0.05 ml is injected into each 18-day-old embryonated broiler chicken egg using *in ovo* equipment. The vaccine is delivered to the amnion sac.

**Proposed dilutions for *in ovo* administration:**

| Number of vaccine ampoules | Solvent | Volume of one dose |
|---|---|---|
| 4 x 2000 doses | 400 ml | 0.05 ml |
| 2 x 4000 doses | 400 ml | |
| 4 x 4000 doses | 800 ml | |
| 1 x 8000 doses | 400 ml | |
| 2 x 8000 doses | 800 ml | |
| 2 x 8000 + 1x 4000 doses | 1000 ml | |
| 3 x 8000 doses | 1200 ml | |
| 4 x 8000 doses | 1600 ml | |

<u>Subcutaneous administration</u>
One single injection of 0.2 ml per chick is applied at one day of age. Automatic syringe is recommended to use. The vaccine is delivered under the skin of the neck.

**Proposed dilutions for subcutaneous administration:**

| Number of vaccine ampoules | Solvent | Volume of one dose |
|---|---|---|
| 1 x 2000 doses | 400 ml | 0.2 ml |
| 2 x 2000 doses | 800 ml | |
| 1 x 4000 doses | 800 ml | |
| 3 x 2000 doses | 1200 ml | |
| 1 x 8000 doses | 1600 ml | |

Preparation of vaccine:

1. After matching the dose size of the vaccine with the solvent (*Cevac Solvent Poultry)* size, quickly remove from liquid nitrogen container the exact number of ampoules needed.
2. Draw up 2-5 ml of solvent into a 5-10 ml sterile syringe. Use at least 18 gauge needles.
3. Thaw rapidly the contents of the ampoules by gentle agitation in water at 27-39 °C.
4. As soon as they are completely thawed, open ampoules holding them at arm's length in order to prevent any risk of injury should the ampoule break.
5. Once the ampoule is open slowly draw up the content into the needle already containing 2-5 ml solvent.
6. Transfer the suspension into the solvent bag. The diluted vaccine prepared as described is mixed by gentle agitation.
7. Withdraw a portion of the diluted vaccine into the syringe to rinse ampoule. Remove the washing from the ampoule and inject it gently into the solvent bag. Repeat it one or two times.
8. The diluted vaccine prepared as described is mixed by gentle agitation so as to be ready for use.

Repeat the operations in point 2-7 for the appropriate number of ampoules to be thawed.

The reconstituted vaccine is orange to red, clear to opaque suspension. Insoluble particles may be present.

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

No adverse events other than those mentioned in section 3.6 were observed after the administration of a 10-fold overdose of vaccine to chicks having MDA against IBDV.

### 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

To stimulate active immunity against avian IBD viruses (gumboro disease).

Live viral vaccine in immune complex.
The vaccine contains a live intermediate plus strain of IBD virus bound to specific immunoglobulins. The two components form a complex which is administered through vaccination.

## 5. PHARMACEUTICAL PARTICULARS

### 5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product except the solvent *(Cevac Solvent Poultry)* supplied for use with the veterinary medicinal product.

### 5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life of the solvent as packaged for sale: 30 months.

Shelf life after reconstitution according to directions: 2 hours at a temperature below 25°C.

### 5.3 Special precautions for storage

Vaccine:
Store and transport frozen in liquid nitrogen (-196°C).
The liquid nitrogen containers must be checked regularly for liquid nitrogen level and must be refilled as needed.

Solvent:
Store below 25°C.
Do not freeze.

### 5.4 Nature and composition of immediate packaging

Vaccine:
One type I glass ampoule of 2 ml containing 2000 or 4000 doses.
One type I glass ampoule of 5 ml containing 2000, 4000 or 8000 doses.

Ampoules are put on cane, supplied with tag showing the number of doses.
The canes with ampoules are stored in a liquid nitrogen container.

Solvent: Polyvinylchloride bag containing 400 ml, 800 ml, 1000 ml, 1200 ml or 1600 ml in individual over-pouch.

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-Phylaxia Veterinary Biologicals Co. Ltd,

## 7. MARKETING AUTHORISATION NUMBER(S)

VPA10463/009/001

## 8. DATE OF FIRST AUTHORISATION

07 August 2020

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

03 January 2025

## 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).