SUMMARY OF PRODUCT CHARACTERISTICS

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:
Live attenuated IBD virus, Serotype 1, strain G-61 (Winterfield 2512) 0.7 – 2.7 log10 CID_{50}*

Excipients:
BDA (Bursal Disease Antibody) 1.5 – 2.04 log10 AB unit**

For the full list of excipients, see section 6.1.

* Chicken Infective Dose 50%
** Antibody unit

3. PHARMACEUTICAL FORM

Concentrate and solvent for suspension for injection

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

4. CLINICAL PARTICULARS

4.1 Target species

Chickens and embryonated chicken eggs (broilers).

4.2 Indications for use, specifying the 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 is 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.

4.3 Contraindications

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

4.4 Special warnings for each target species

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

4.5 Special precautions for use

Special precautions for use in animals

Vaccinated chickens may excrete the vaccine strain up to 21 days following the vaccine virus take.
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.

4.6 Adverse reactions (frequency and seriousness)

In vaccinated chickens, mild to moderate lymphocyte depletion is very common, 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.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports)

4.7 Use during pregnancy, lactation or lay

Not applicable.

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

The vaccine can be administered by *in ovo* or via subcutaneous routes.
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.

In ovo administration
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	

Subcutaneous administration

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.

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

No adverse reactions other than those mentioned in section 4.6 were observed after the administration of a ten dose of vaccine to chicks having MDA against IBDV.

4.11 Withdrawal period(s)

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

Live viral vaccine in immune complex.
To stimulate active immunity against infectious bursal disease viruses.
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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Vaccine:
BDA (bursal disease antibody)
sucrose
water for injection

Solvent (Cevac Solvent Poultry):
sucrose
casein hydrolysate
sorbitol
dipotassium hydrogen phosphate
potassium dihydrogen phosphate
phenol red
water for injection

6.2 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.

6.3 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.

6.4 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.

6.5 Nature and composition of immediate packaging

Vaccine:
One type I glass ampoule of 2 ml containing 2,000 or 4,000 doses or
One type I glass ampoule of 5 ml containing 2,000, 4,000 or 8,000 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.

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

Ceva Animal Health Ltd
Explorer House
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Wooburn Green
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Buckinghamshire
HP10 0HH
United Kingdom

8. MARKETING AUTHORISATION NUMBER

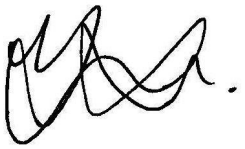
Vm 15052/4154

9. DATE OF FIRST AUTHORISATION

13 August 2020

10. DATE OF REVISION OF THE TEXT

October 2022



Approved: 11 October 2022