SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Novamune concentrate and solvent for suspension for injection for chickens

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose (0.2 ml) contains:

Active substance:
Live attenuated IBD virus, Serotype 1, strain SYZA26 2.65 – 4.2 log10 CID_{50}*

Excipients:
BDA (Bursal Disease Antibody) 1.3 – 2.2 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 concentrate: reddish-brownish frozen suspension.
Solvent: clear, orange to red liquid.

4. CLINICAL PARTICULARS

4.1 Target species

Chickens

4.2 Indications for use, specifying the target species

For active immunisation of day-old future layer chickens in order to reduce clinical signs and acute lesions of bursa of Fabricius caused by very virulent Avian Infectious Bursal Disease (IBD) virus infection.

Onset of immunity is expected from 30 days 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. The

onset of clinical protection depends on the initial MDA level. In vaccinated day old future layer chicks the release of the vaccine virus (vaccine virus take) was observed between 21-42 days after vaccination.

Duration of immunity: 9 weeks.
The virulent challenge tests conducted to support the claim were carried out on day old future layer chicks having MDA ELISA titre of 3,000 to 5,700 (average Day 0 MDA levels).
Field trials carried out showed that vaccine virus replication in the bursa of Fabricius occurs in day old future layer chicks having average MDA titre levels of 6,000 ELISA units.

4.3 Contraindications

Do not vaccinate chickens from non-vaccinated parent flocks or having no MDA against IBDV as vaccination of such birds may cause immunosuppression.

4.4 Special warnings for each target species

Vaccinate healthy birds only.
Vaccinate only MDA positive birds which have at least an average day-old MDA level of 2500 ELISA units (this MDA level was determined from studies which used a commercially available ELISA kit from BioCheck).

4.5 Special precautions for use

Special precautions for use in animals

Vaccinated chickens may excrete the vaccine strain up to 14 days following the vaccine virus take. During this time, the contact of immunosuppressed and unvaccinated chickens 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.

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 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

Laying birds:
Do not use in birds in lay and within 4 weeks before the start of the laying period.

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 must be administered by subcutaneous route

The vaccine is to be administered once at 1 day of age. Automatic syringe may be used. The injection volume is 0.2 ml per dose. The vaccine is delivered under the skin of the neck. Use sterile devices and equipment for reconstitution and for administration of the vaccine.

Proposed dilutions for subcutaneous administration:

Number of vaccine ampoules	Solvent	Volume of one dose
2 x 500 doses	200 ml	0.2 ml
4 x 500 doses	400 ml	
8 x 500 doses	800 ml	
1 x 1000 doses	200 ml	
2 x 1000 doses	400 ml	
4 x 1000 doses	800 ml	
1 x 2000 doses	400 ml	
2 x 2000 doses	800 ml	

2 x 2000 + 1 x 1000 doses	1000 ml	
3 x 2000 doses	1200ml	
4 x 2000 doses	1600 ml	

Preparation of vaccine:

1. After matching the dose size of the vaccine ampoule(s) with the solvent 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 vaccine prepared as described is mixed by gentle agitation.
7. Withdraw a portion of the 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 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.

Do not use Novamune if you notice visible signs of unacceptable decolourisation in the vials. 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

Ten times the maximum dose was shown to be safe for commercial layer 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 (Gumborodisease)

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

Solvent:
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

Vaccine concentrate:
Shelf life of the veterinary medicinal product as packaged for sale: 2 years.

Solvent:
Shelf life of the solvent as packaged for sale: 30 months

Shelf life after reconstitution according to directions: 2 hours.

6.4 Special precautions for storage

Vaccine concentrate:
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 concentrate:
One type I glass ampoule of 2 ml containing 500 or 1,000 doses or
one type I glass ampoule of 5 ml containing 500, 1,000 or 2,000 doses.
Ampoules are put on cane, supplied with tag showing the dose.
The canes with ampoules are stored in a liquid nitrogen container.

Solvent: Polyvinylchloride bag containing 200 ml, 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
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8. MARKETING AUTHORISATION NUMBER

Vm 15052/5032

9. DATE OF FIRST AUTHORISATION

7 November 2018

10. DATE OF REVISION OF THE TEXT

March 2023

Approved 07 March 2023