ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Ampoule of vaccine 500, 1000, 2000 doses

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Novamune

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

IBDV

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

500 doses
1000 doses
2000 doses
(on the tag)

4. ROUTE(S) OF ADMINISTRATION

SC

5. WITHDRAWAL PERIOD(S)

6. BATCH NUMBER

Lot {number}

7. EXPIRY DATE

EXP

Store: -196°C

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

Ceva-Phylaxia Co. Ltd.

PARTICULARS TO APPEAR ON IMMEDIATE PACKAGING (LABEL) OF THE DILUENT

Solvent bag, 200 ml, 400 ml, 800 ml, 1000 ml, 1200 ml, 1600 ml

1. NAME OF THE DILUENT

Cevac Solvent Poultry

2. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

200 ml
400 ml
800 ml
1000 ml
1200 ml
1600 ml

3. ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

4. STORAGE CONDITIONS

Store below 25°C.
Do not freeze.

5. BATCH NUMBER

Lot {number}

6. EXPIRY DATE

EXP

7. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

Company Logo

or

CEVA-Phylaxia Co. Ltd.
1107 Budapest
Szállás u. 5.
Hungary

B. PACKAGE LEAFLET

PACKAGE LEAFLET:

Novamune concentrate and solvent for suspension for injection for chickens

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:
Ceva Animal Health Ltd
Explorer House
Mercury Park
Wycombe Lane
Wooburn Green
High Wycombe
Buckinghamshire
HP10 0HH
United Kingdom

Manufacturer responsible for batch release:
CEVA-Phylaxia Co. Ltd.
1107 Budapest
Szállás u 5.
Hungary

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Novamune concentrate and solvent for suspension for injection for chicken

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

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**

* Chicken Infective Dose 50%
** Antibody unit

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

4. INDICATION(S)

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.

5. CONTRAINDICATIONS

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

6. ADVERSE REACTIONS

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)

If you notice any side effects, even those not already listed in this package leaflet or you think that the
medicine has not worked, please inform your veterinary surgeon.

7. TARGET SPECIES

Chickens

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

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	

9. ADVICE ON CORRECT ADMINISTRATION

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.

10. WITHDRAWAL PERIOD(S)

Zero days

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

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.

Do not use this veterinary medicinal product after the expiry date which is stated on the label. The expiry date refers to the last day of that month.
Shelf life after reconstitution according to directions: 2 hours.

12. SPECIAL WARNING(S)

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).

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.

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

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.

Overdose (symptoms, emergency procedures, antidotes):
Ten times the maximum dose can cause decreased weight gain in SPF birds but was shown to be safe for commercial layer chicks having MDA against IBDV.

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

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

October 2022

15. OTHER INFORMATION

Vm 15052/5032

Vaccine concentrate:
1x glass ampoule of 2 ml containing 500 or 1,000 doses.

1x 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, 400, 800, 1000, 1200 or 1600 ml of solvent (Cevac Solvent Poultry) in individual over-pouch.

Not all pack sizes may be marketed.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

Approved 07 March 2023