ANNEX I

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:
Infectious bursal disease virus,
serotype 1, strain SYZA26 (intermediate plus), live attenuated 2.5 – 4.2 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 concentrate:	
BDA (Bursal Disease Antibody)	1.3 – 2.2 log10 AB unit**
Sucrose	
Water for injections	
Solvent:	
Sucrose	
Casein hydrolysate	
Sorbitol	
Dipotassium hydrogen phosphate	
Potassium dihydrogen phosphate	
Phenol red	
Water for injections	

** Antibody unit

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

3. CLINICAL INFORMATION

3.1 Target species

Chickens

3.2 Indications for use for each 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: expected from 30 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. 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: up to 9 weeks of age.

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.

3.3 Contraindications

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

3.4 Special warnings

Vaccinate healthy animals 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).

3.5 Special precautions for use

Special precautions for safe use in the target species:

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.

Special precautions for the protection of the environment:

Not applicable

3.6 Adverse events

Chickens:

Very common (>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

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

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 must be administered by subcutaneous use.

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	1200 ml	
4 x 2000 doses	1600 ml	

Preparation of vaccine:

1. After matching the dose size of the vaccine ampoule(s) 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 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.

The vaccine should not be used if there are visible signs of unacceptable decolourisation in the vials.

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 commercial layer 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

3.12 Withdrawal periods

Zero days.

4. IMMUNOLOGICAL INFORMATION

4.1 ATCvet code: QI01AD09

To stimulate active immunity against IBD viruses.
Live viral vaccine in immune complex.

The vaccine contains a live intermediate plus strain of IBD virus bound to specific immunoglobulins (BDA). The two components form an immune 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 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.

5.4 Nature and composition of immediate packaging

Vaccine concentrate:
One type I glass ampoule of 2 ml containing 500 or 1000 doses.
One type I glass ampoule of 5 ml containing 500, 1000 or 2000 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 200 ml, 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

7. MARKETING AUTHORISATION NUMBER(S)

8. DATE OF FIRST AUTHORISATION

Date of first authorisation:

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

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).

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Ampoule of vaccine and tag 500, 1000, 2000 doses

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Novamune

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

IBDV

3. BATCH NUMBER

Lot {number}
(on the tag as well)

500 doses
1000 doses
2000 doses
(on the tag)

4. EXPIRY DATE

Exp. {mm/yyyy}

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

Solvent bags of 200 ml, 400 ml, 800 ml, 1000 ml, 1200 ml or 1600 ml

1. NAME OF THE DILUENT

Cevac Solvent Poultry

2. TARGET SPECIES

3. ROUTE(S) OF ADMINISTRATION

Read package leaflet before use.

4. EXPIRY DATE

Exp. {month/year}

5. SPECIAL STORAGE PRECAUTIONS

Store below 25 °C.
Do not freeze.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Company logo or name of the company

7. BATCH NUMBER

Lot {number}

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

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Novamune concentrate and solvent for suspension for injection for chickens

2. Composition

Each dose (0.2 ml) contains:

Active substance:

Infectious bursal disease virus,
serotype 1, strain SYZA26 (intermediate plus), live attenuated 2.5 – 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.

3. Target species

Chickens

4. Indications for use

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: expected from 30 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. 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: up to 9 weeks of age.

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 use in chickens from non-vaccinated parent flocks or having no MDA against IBDV as vaccination of such birds may cause immunosuppression.

6. Special warnings

Special warnings:

Vaccinate healthy animals 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 safe use in the target species:

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.

Laying birds:

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:

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

Special restrictions for use and special conditions for use:

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.

7. Adverse events

Chickens:

Very common (>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 product. 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 contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or its local representative using the contact details at the end of this leaflet, or via your national reporting system. {national system details}

8. Dosage for each species, routes and method of administration

The vaccine must be administered by subcutaneous use.

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	1200 ml	
4 x 2000 doses	1600 ml	

Preparation of vaccine:
1. After matching the dose size of the vaccine ampoule(s) 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 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.

9. Advice on correct administration

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

The vaccine should not be used if there are visible signs of unacceptable decolourisation in the vials.

10. Withdrawal periods

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 after Exp. The expiry date refers to the last day of that month.

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

12. Special precautions for disposal

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 applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription

14. Marketing authorisation numbers and pack sizes

Vaccine concentrate:
One type I glass ampoule of 2 ml containing 500 or 1000 doses.
One type I glass ampoule of 5 ml containing 500, 1000 or 2000 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 200, 400, 800, 1000, 1200 or 1600 ml of solvent (Cevac Solvent Poultry) in individual over-pouch.

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

16. Contact details

Marketing authorisation holder and contact details to report suspected adverse events:

Manufacturer responsible for batch release:

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

17. Other information

This vaccine is designed to stimulate active immunity against IBD viruses. It contains a live intermediate plus strain of the IBD virus, which is bound to specific immunoglobulins (BDA), forming an immune complex.
Upon administration, this complex protects the live virus from early neutralization by maternal antibodies, allowing controlled viral release and ensuring an uniform immune response.