1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cevac Transmune lyophilisate and solvent for suspension for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose of reconstituted vaccine (0.05 ml in-ovo or 0.1 ml subcutaneous) contains:

Active substances:

Infectious bursal disease (IBD) virus, strain Winterfield 2512 (intermediate plus), live, attenuated at least 0.1 CID_{50}*
* 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**
Lyophilisate:	
BDA (bursal disease antibody)	at least 90 VN titre**
Cyclodextrin	
Sucrose	
Monosodium glutamate	
Potassium dihydrogen phosphate	
Dipotassium hydrogen phosphate	
Solvent (PBS):	
Sodium chloride	
Potassium chloride	
Disodium phosphate dihydrate	
Potassium dihydrogen phosphate	
Water for injections	
Solvent (Saline solution):	
Sodium chloride	
Water for injections	
Solvent (Cevac Solvent Poultry):	
Sucrose	
Casein hydrolysate	
Sorbitol	
Dipotassium hydrogen phosphate	

Potassium dihydrogen phosphate	
Phenol red	
Water for injections	

** VN titre (virus neutralisation titre)

Lyophilisate: pale brown
Solvent: water-clear, colourless or clear red

3. CLINICAL INFORMATION

3.1 Target species

Chickens (one day-old chicks and embryonated eggs).

3.2 Indications for use for each target species

For the active immunisation of 18-day-old embryonated broiler hatching eggs or 1-day-old broiler chickens from hens vaccinated against avian infectious bursal disease virus (IBDV), to reduce mortality, clinical disease, weight loss and acute lesions of bursa of Fabricius associated with infection caused by very virulent avian infectious bursal disease viruses.

Onset of immunity: between 21 and 32 days of age.
Duration of immunity: up to 6 weeks of age.

3.3 Contraindications

Do not use in eggs or in 1-day-old chickens coming from broiler breeder flocks not vaccinated according to an IBDV immunisation program. (Refer to section 3.5.)

Do not use in1-day-old chickens hatched from eggs vaccinated in-ovo with veterinary medicinal product.

3.4 Special warnings

Vaccinate healthy animals only.

Chicken embryos on the 18th day of incubation
In-ovo injection equipment must be used for in-ovo administration. Device(s) used for the reconstitution of the vaccine and for injection should be sterile and free from any residues of chemical disinfectant.
The device should be proven to safely and effectively deliver the appropriate 0.05 ml dose of the vaccine directly into the amniotic cavity or the embryo.
Before every in-ovo application the vaccination technique can be checked by use of a colour solution. The manufacturer's instructions of the device must be strictly followed. For cleaning of the instrument only products approved by the manufacturer may be used.
It is recommended to use 0.4-0.8 mm diameter needles, having length from 25-28 mm and perforation air pressure between 3.5 bar (50 psi) and 5 bar (72 psi).

1-day-old broiler chickens
Automatic syringe may be used for subcutaneous administration. Device(s) used for the reconstitution of the vaccine and for injection should be sterile and free from any residues of chemical disinfectant. The device should be proven to safely and effectively deliver the appropriate 0.1 ml dose of the vaccine. The instructions for use of this device should be strictly followed.
The vaccine must be inoculated under the skin of the neck of the 1-day-old broiler chickens. For cleaning of the automatic syringe, only products approved by the manufacturer may be used.

Residues of chemical disinfectant on the inner surface of devices and equipment used for reconstitution and application can destroy live virus and decrease the efficacy of the vaccine.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Chicken embryos on the 18th day of incubation
The vaccine contains a strain of "intermediate-plus" virulence. In birds without MDA the inoculation of the vaccine results in significant immunosuppression and bursal damage. Therefore, it is not recommended to vaccinate eggs coming from flocks with MDA titre levels in 1-day-old chickens lower than 3,000 ELISA units.
Preliminary survey to be used to estimate MDA level of the chicks: 20, 1-day-old chicks originating from the same breeding flock should be sampled to measure their serological status to IBDV. The results of this sampling will indicate if the MDA level can be expected to be at least 3,000 ELISA units in the hatches of the following 4 weeks from this flock, and therefore that they are suitable for veterinary medicinal product vaccination. According to results and needs, this survey has to be repeated at different times of the laying period.
The vaccine virus is excreted by vaccinated birds and can spread to susceptible birds and can be detected in unvaccinated birds 4-7 days later. To control the spread of the virus, the immunisation devices used for injection and the hatchery premises should be decontaminated after vaccination.

Chickens from vaccinated eggs should not be mixed with chickens from unvaccinated eggs.
Precautions should be taken regarding between-house spread. Whole site vaccination is recommended.
Poultry houses should be decontaminated between batches of chickens.

Satisfactory protection can be achieved only in properly developed embryos at the 18th day of hatching. It is suggested to candle the eggs to be injected and discard eggs containing dead embryos.

1-day-old broiler chickens
The vaccine contains a strain of "intermediate-plus" virulence. In birds without MDA the inoculation of the vaccine results in significant immunosuppression and bursal damage. Therefore, it is not recommended to vaccinate chicks coming from flocks with 1-day-old MDA titre levels lower than 3,000 ELISA units.
Preliminary survey to be used to estimate MDA level of the chicks: 20, 1-day-old chicks originating from the same breeding flock should be sampled to measure their serological status to IBDV. The results of this sampling will indicate if the MDA level can be expected to be at least 3,000 ELISA units in the hatches of the following 4 weeks from this flock, and therefore that they are suitable for vaccination with the veterinary medicinal product. According to results and needs, this survey has to be repeated at different times of the laying period.
The vaccine virus is excreted by vaccinated birds and can spread to susceptible birds and can be detected in unvaccinated birds 4-7 days later. To control the spread of the virus, the immunisation devices used for injection and the hatchery premises should be decontaminated after vaccination.

Vaccinated chickens should not be mixed with unvaccinated chickens.
Precautions should be taken regarding between-house spread. Whole site vaccination is recommended.
Poultry houses should be decontaminated between batches of chickens.

Satisfactory protection can be achieved only in healthy 1-day-old chickens.

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

Vaccinating personnel should wash and disinfect hands after use.
In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Target species: Chickens (one day-old chicks and embryonated eggs).

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

[1] Mild to moderate lymphocyte depletion 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. In some cases, the replication of the vaccine strain may be prolonged (e.g. due to presence of very high maternal antibody titres in 1-day-old chicks), and bursa scores can reach a maximum of 2.8 between 35 and 42 days of age, which does not affect the production parameters of the flock.

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 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

Do not use in eggs intended for hatching of layers or broiler breeders.
Do not use in 1-day-old chickens intended for layers or broiler breeders.

3.8 Interaction with other medicinal products and other forms of interaction

Safety and efficacy data are available which demonstrate that this vaccine can be mixed and administered with Vectormune ND by in-ovo or subcutaneous vaccination. The mixed products protect against avian infectious bursal disease viruses, Newcastle disease virus and Marek's disease virus. The safety and efficacy of the mixed vaccines are not different from those described for the vaccines administered separately. Read also the product information of Vectormune ND before use.
For the associated reconstitution of Vectormune ND and Cevac Transmune, the Cevac Solvent Poultry should be used.

In-ovo:
One single dose of 0.05 ml is injected into each 18-day-old embryonated broiler chicken egg.
Match the dose size of the vaccines and the Cevac Solvent Poultry according to the table below.

Vectormune ND	Cevac Transmune	Cevac Solvent Poultry
2 x 2,000 doses	2 x 2,000 doses	200 ml
1 x 4,000 doses	1 x 4,000 doses	200 ml
2 x 4,000 doses	2 x 4,000 doses	400 ml
4 x 4,000 doses	4 x 4,000 doses	800 ml
5x4,000 doses	5x4,000 doses	1,000 ml
6x4,000 doses	6x4,000 doses	1,200 ml
8x4,000 doses	8x4,000 doses	1,600 ml

Subcutaneous use:
One single injection of 0.2 ml per chick is applied at one day of age.
Match the dose size of the vaccines and the Cevac Solvent Poultry according to the table below.

Vectormune ND	Cevac Transmune	Cevac Solvent Poultry

2 x 1,000 doses	1 x 2,000 doses	400 ml
1 x 2,000 doses	1 x 2,000 doses	400 ml
2 x 2,000 doses	2 x 2,000 doses	800 ml
1 x 4,000 doses	1 x 4,000 doses	800 ml
4,000 + 1,000 doses	4,000 + 1,000 doses	1,000 ml
3 x 2,000 doses	3 x 2,000 doses	1,200 ml
2 x 4,000 doses	2 x 4,000 doses	1,600 ml

Draw up 2 ml of Cevac Solvent Poultry into a 5 ml syringe then draw up the thawed content of Vectormune ND ampoule in it.
Draw up 2 ml of Cevac Solvent Poultry into another 5 ml syringe then dissolve the content of Cevac Transmune vial in it.
Transfer the dissolved vaccines into the solvent bag and mix by gentle agitation.

No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product, except Vectormune ND. 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

In-ovo:
The vaccine is to be administered once at the 18th day of embryonation using in-ovo equipment. The injection volume is 0.05 ml per dose for in-ovo administration. The vaccine is delivered to the amnion sac or, rarely, into the body of the embryo causing no decrease in hatchability.
Use sterile devices and equipment for reconstitution and for administration of the vaccine.

Subcutaneous use:
The vaccine is to be administered once at 1-day of age, automatic syringe may be used. The injection volume is 0.1 ml per dose for subcutaneous administration. The vaccine is delivered under the skin of the neck.
Use sterile devices and equipment for reconstitution and for administration of the vaccine.

Reconstitution of the vaccine
For the reconstitution of veterinary medicinal product, PBS, Saline solution or Cevac Solvent Poultry can be used.

In-ovo of 0.05 ml per dose:

1. Calculate and prepare the required volume of the reconstituted vaccine as follows:

Veterinary medicinal product	Solvent
1 x 2,000 doses	100 ml
1 x 4,000 doses	200 ml
1 x 5,000 doses	250 ml
2 x 2,500 doses	250 ml
2 x 4,000 doses	400 ml
2 x 5,000 doses	500 ml
4 x 4,000 doses	800 ml
4 x 5,000 doses	1,000 ml
1 x 8,000 doses	400 ml
6 x 4,000 doses	1,200 ml
8 x 4,000 doses	1,600 ml

2. Draw up 2 ml of the solvent and transfer into the glass vial containing the lyophilised component.
3. Completely dissolve the vaccine by shaking gently and transfer it into the plastic solvent bottle.
4. Rinse the vial with another 2 ml liquid and transfer the rinsing liquid into the plastic solvent bottle.

5. Repeat this rinsing operation.

Administration of the vaccine:
Follow the User Manual instructions for the in-ovo injector equipment.
The reconstituted vaccine should be used within 2 hours.

Subcutaneous use of 0.1 ml per dose:
1. Calculate and prepare the required volume of the reconstituted vaccine as follows:

Veterinary medicinal product	Solvent
1 x 2,000 doses	200 ml
1 x 2,500 doses	250 ml
1 x 4,000 doses	400 ml
1 x 5,000 doses	500 ml
2 x 4,000 doses	800 ml
2 x 5,000 doses	1,000 ml
1 x 8,000 doses	800 ml
3 x 4,000 doses	1,200 ml
4 x 4,000 doses	1,600 ml

2. Draw up 2 ml of the solvent and transfer into the glass vial containing the lyophilised component.
3. Completely dissolve the vaccine by shaking gently and transfer it into the plastic solvent bottle.
4. Rinse the vial with another 2 ml liquid and transfer the rinsing liquid into the plastic solvent bottle.
5. Repeat this rinsing operation.

Administration of the vaccine:
Follow the User Manual instructions for the automatic syringe.
The reconstituted vaccine should be used within 2 hours.

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

No adverse events were observed other than those reported under section 3.6 “Adverse events”, when a 10-fold overdose was administered.

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 very virulent infectious bursal disease viruses in broiler chickens from hens vaccinated against IBDV. The vaccine contains the live intermediate plus IBDV strain Winterfield 2512 bound to specific immunoglobulins. Both components form a complex which is administered through vaccination. The Winterfield 2512 vaccine virus, applied as a non-immune-complex vaccine results in a mean histological lesion score of 2.2 in the bursa of Fabricius, 28 days after vaccination (after oral vaccination of 1-

day-old SPF chicken with 10 doses). The severity and duration of lesions is less significant following administration of the immune-complex vaccine.

The release of the vaccine virus from the complex (and therefore immunisation) is influenced by the natural decline of maternally derived antibodies (MDA) and has been found not to occur until MDA has reached relatively low levels.
The onset of clinical protection depends on the initial MDA level. In vaccinated broilers it is achieved within 1 day after the first signs of vaccine virus effect in the bursa of Fabricius.

The virulent challenge tests conducted to support the claim were carried out on broilers having an MDA ELISA titre of 6,000 (1-day-old chicks).
Field trials carried out showed that vaccine virus replication in the bursa of Fabricius occurs in broilers having at hatch MDA titre levels of up to 14,000 ELISA units, but the protection of these birds was evaluated only based on serological data and histology of the bursa of Fabricius.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product, except Vectormune ND and the solvents supplied for use with the veterinary medicinal product.

5.2 Shelf life

Shelf life of the lyophilisate as packaged for sale: 2 years.
Shelf life of the solvent (PBS) as packaged for sale: 43 months.
Shelf life of the solvent (Saline solution) as packaged for sale:

- Polyolefin based plastic bags equipped with infusion port, rubber stopper with flip off cap: 33 months.
- Polyolefin based plastic bags equipped with single or double tubes, closed with injection port or rubber stopper with flip off cap: 2 years.

Shelf life of the solvent (Cevac Solvent Poultry) as packaged for sale: 30 months.

Shelf-life after reconstitution (in PBS, Saline solution or Cevac Solvent Poultry) according to directions: 2 hours.

5.3 Special precautions for storage

Lyophilisate: store and transport refrigerated (2°C – 8°C).
Protect from light.

Solvents: store below 25°C.
Do not freeze.

5.4 Nature and composition of immediate packaging

Lyophilisate:
Cardboard box with single or 20 glass vials (Type I) of 10 ml containing 2000, 2500, 4000 or 5000 doses, and of 13.5 ml containing 8000 doses, closed with a bromobutyl stopper and sealed with aluminium caps with plastic tear-off centres.

Solvent (PBS):
Cardboard box with single, 5 or 20 plastic bottles (LDPE), of 100, 200, 250, 400 or 500 ml solvent, closed with a bromobutyl stopper and sealed with aluminium caps with plastic tear-off centres.

Solvent (Saline solution):

- Polyolefin based plastic bags equipped with infusion port, rubber stopper with flip off cap: 500 ml, 1000 ml, 5 x 500 ml, 5 x 1000 ml.
- Polyolefin based plastic bags equipped with single or double tubes, closed with injection port or rubber stopper with flip off cap: 250 ml, 500 ml, 1000 ml, 5 x 250 ml, 5 x 500 ml, 5 x 1000 ml.

Solvent (Cevac Solvent Poultry):
Polyvinylchloride bag containing 200 ml, 400 ml, 800 ml, 1000 ml, 1200 ml, 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 Santé Animale

7. MARKETING AUTHORISATION NUMBER(S)

VPA10815/005/001

8. DATE OF FIRST AUTHORISATION

26/11/2007

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

30/07/2026

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).