PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARDBOARD BOX LABEL / LYOPHILISATE 2,000, 2,500, 4,000, 5,000, 8,000 doses

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cevac Transmune lyophilisate and solvent for suspension for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Live attenuated IBD virus, strain Winterfield 2512 min. 0.1 *CID_{50} per dose
BDA at least 90 VN titre** per dose

*CID_{50} (Chicken Infective Dose 50%),
** VN titre (virus neutralisation titre)

3. PACKAGE SIZE

2,000 doses
2,500 doses
4,000 doses
5,000
8,000 doses
20 X 2,000 doses
20 X 2,500 doses
20 X 4,000 doses
20 X 5,000
20 X 8,000 doses

4. TARGET SPECIES

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

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

In-ovo or subcutaneous use.

7. WITHDRAWAL PERIODS

Withdrawal period: Zero days.

8. EXPIRY DATE

Exp. {dd/mm/yyyy}
Once reconstituted use within 2 hours.

9. SPECIAL STORAGE PRECAUTIONS

Store and transport refrigerated.
Protect from light.

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Ceva Sante Animale

14. MARKETING AUTHORISATION NUMBERS

Vm 14966/5005
Vm 14966/3004

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

VIAL LABEL / LYOPHILISATE – 2,000, 2,500, 4,000, 5,000, 8,000 doses

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cevac Transmune

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

IBDv

2,000 doses
2,500 doses
4,000 doses
5,000 doses
8,000 doses

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {dd/mm/yyyy}

PARTICULARS TO APPEAR ON THE IMMEDIATE LABEL OF THE DILUENT/SOLVENT
(normal sized bottles)

BOX & CONTAINER LABEL / SOLVENT:

1. NAME OF THE DILUENT/SOLVENT

Cevac Transmune sterile vaccine solvent (PBS)
Cevac Transmune sterile vaccine solvent (Saline solution)
Cevac Solvent Poultry

2. PACKAGE SIZE

100 ml, 200 ml, 250 ml, 400 ml, 500 ml
5 x 100 ml, 5 x 200 ml, 5 x 250 ml, 5 x 400 ml, 5 x 500 ml
20 x 100 ml, 20 x 200 ml, 20 x 250 ml, 20 x 400 ml, 20 x 500 ml

250 ml, 500 ml, 1000 ml
5 x 250 ml, 5 x 500 ml, 5 x 1000 ml

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

3. TARGET SPECIES

Read the package leaflet before use.

4. ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

5. EXPIRY DATE

Exp. {month/year}

6. SPECIAL STORAGE PRECAUTIONS

Store below 25 °C.
Do not freeze.

7. NAME OF THE MARKETING AUTHORISATION HOLDER

Ceva Sante Animale

8. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Cevac Transmune lyophilisate and solvent for suspension for injection

2. Composition

Active substance:

Infectious bursal disease (IBD) virus, strain Winterfield 2512 (intermediate plus), live, attenuated at least 0.1 CID_{50}* per dose), combined with bursal disease antibody (at least 90 VN titre**) presented as a multidose lyophilised vaccine.

*CID_{50} (Chicken Infective Dose 50%)
** VN titre (virus neutralisation titre)

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

3. Target species

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

4. Indications for use

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

5. 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.
Do not use in 1-day-old chickens hatched from eggs vaccinated in-ovo with veterinary medicinal product.

6. Special warnings

Special warnings:
Vaccinate healthy animals only.

Special precautions for safe use in the target species:
In-ovo administration:
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.
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.
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).

Subcutaneous administration:
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. 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. 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.

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 is variable depending 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 test 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 occurred 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.

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 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. 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 or in healthy 1-day-old broiler chicken. It is suggested to candle the eggs to be injected and discard eggs containing dead embryos before in-ovo vaccination.

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.

Laying birds:
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.

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
5 x 4,000 doses	5 x 4,000 doses	1,000 ml
6 x 4,000 doses	6 x 4,000 doses	1,200 ml
8 x 4,000 doses	8 x 4,000 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.

Overdose:
No adverse reactions were observed other than stated in relevant section, when a 10-fold overdose was administered.

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.

7. 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 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 using the contact details at the end of this leaflet, or via your national reporting system at:
Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine
e-mail: adverse.events@vmd.gov.uk

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

Use by the in-ovo or the subcutaneous route:
0.05 ml of veterinary medicinal product should be injected into the embryonated egg on the 18th day of embryonation. The vaccine is delivered to the amnion sac or, rarely, into the body of the embryo causing no decrease in hatchability
or
0.1 ml of veterinary medicinal product should be injected subcutaneously, under the skin of the neck of 1-day-old broiler chickens.

9. Advice on correct administration

The vaccine is to be administered once using in-ovo equipment, or automatic syringe for subcutaneous administration.
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 administration 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 administration 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.

10. Withdrawal periods

Zero days.

11. Special storage precautions

Keep out of the sight and reach of children.

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

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

Do not use this veterinary medicinal product after the expiry date which is stated on the label.

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

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.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 14966/5005
Vm 14966/3004

Pack sizes of lyophilisate: 2,000, 2,500, 4,000, 5,000, 8,000 doses, 1 or 20 vials in a cardboard box
Pack sizes of solvent (PBS): 100, 200, 250, 400, 500 ml, 1, 5 or 20 bottles in a cardboard box

Pack sizes of solvent (Saline solution): 250, 500, 1,000 ml, 1 or 5 polyolefin based plastic bags in a cardboard box
Pack sizes of solvent (Cevac Solvent Poultry): 200, 400, 800, 1,000, 1,200, 1,600 ml polyvinylchloride bag in individual over-pouch.

Not all pack sizes may be marketed.

15. PID link (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

16. Contact details

Marketing authorisation holder and contact details to report suspected adverse events:
Ceva Sante Animale
8 rue de Logrono
33500 Libourne
France

Email: pharmacovigilance@ceva.com
Phone number: +800 35 22 11 51

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

17. Other information

POM-V

Approved 28 August 2026
Gavin Hall