ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARD BOARD BOX LABEL / LYOPHILISATE – 2000, 2500, 4000, 5000, 8000 doses

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

CEVAC Transmune lyophilisate for suspension for injection with solvent, for chickens

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Live, attenuated Winterfield 2512 IBD virus strain (at least 0.1 *CID_{50} per dose) with BDA (at least 90 VN titre**).
*CID_{50} (Chicken Infective Dose 50%), ** VN titre (virus neutralisation titre)

3. PHARMACEUTICAL FORM

Lyophilisate for suspension for injection

4. PACKAGE SIZE

2000 doses
2500 doses
4000 doses
5000
8000 doses
20 X 2000 doses
20 X 2500 doses
20 X 4000 doses
20 X 5000
20 X 8000 doses

5. TARGET SPECIES

Chickens and embryonated chicken eggs.

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

In-ovo or subcutaneous use.
Read the package leaflet before use and disposal.

8. WITHDRAWAL PERIOD

Withdrawal period: Zero days.

9. SPECIAL WARNING(S), IF NECESSARY

Accidental injection is dangerous. Read the package leaflet before use.

10. EXPIRY DATE

<EXP {month/year}>
Once reconstituted use within 2 hours.

11. SPECIAL STORAGE CONDITIONS

Store and transport refrigerated (2 °C - 8°C).
Protect from light.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

16. MARKETING AUTHORISATION NUMBER

Vm 15052/4030

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

VIAL LABEL / LYOPHILISATE – 2000, 2500, 4000, 5000, 8000 doses

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

CEVAC Transmune lyophilisate for suspension for injection with solvent for chickens

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

2000 doses
2500 doses
4000 doses
5000
8000 doses

3. ROUTE(S) OF ADMINISTRATION

In-ovo or subcutaneous use.

4. BATCH NUMBER

Lot {number}

5. EXPIRY DATE

EXP {month/year}

6. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

<PARTICULARS TO APPEAR ON THE OUTER PACKAGE>
<PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE>

BOX & CONTAINER LABEL / SOLVENT: PBS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

CEVAC Transmune
Sterile vaccine solvent (PBS)

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

One in-ovo dose of 0.05 ml or subcutaneous dose of 0.1 ml contains: Sodium and potassium salts in water for injections.

3. PHARMACEUTICAL FORM

Solvent for suspension for injection
Water-clear, colourless liquid.

4. 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

5. TARGET SPECIES

Chickens and embryonated chicken eggs

6. INDICATION(S)

For reconstitution of the lyophilised vaccine.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use and disposal.

8. WITHDRAWAL PERIOD

Withdrawal period: Zero days.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

Store below 25ºC.
Do not freeze.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

16. MARKETING AUTHORISATION NUMBER(S)

Vm 15052/4030

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

<PARTICULARS TO APPEAR ON THE OUTER PACKAGE>
<PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE>

BOX & CONTAINER LABEL / SOLVENT: Saline solution

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

CEVAC Transmune
Sterile vaccine solvent (Saline solution)

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

One in-ovo dose of 0.05 ml or subcutaneous dose of 0.1 ml contains: Sodium salts in water for injections.

3. PHARMACEUTICAL FORM

Solvent for suspension for injection
Water-clear, colourless liquid.

4. PACKAGE SIZE

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

5. TARGET SPECIES

Chickens and embryonated chicken eggs

6. INDICATION(S)

For reconstitution of the lyophilised vaccine.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use and disposal.

8. WITHDRAWAL PERIOD

Withdrawal period: Zero days.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

Store below 25ºC.
Do not freeze.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

16. MARKETING AUTHORISATION NUMBER(S)

Vm 15052/4030

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

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

Cevac Solvent Poultry **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 {month/year}

7. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

Company logo or name of company

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

B. PACKAGE LEAFLET

PACKAGE LEAFLET

CEVAC Transmune lyophilisate for suspension for injection with solvent 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

CEVAC Transmune lyophilisate for suspension for injection with solvent for chickens

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

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

Pale brown lyophilisate for reconstitution with a water-clear, colourless or a clear red solvent provided for injection.

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

4. INDICATION(S)

For the active immunisation of 18-day-old embryonated broiler hatching eggs or 1-day-old broiler chickens from hens vaccinated against IBD, to reduce mortality, clinical disease, weight loss, and acute lesions of bursa of Fabricius associated with infection caused by very virulent infectious bursal disease (IBD) viruses.
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.
Onset of immunity: between 21 and 32 days of age.
Duration of immunity: up to 42 days of age.

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.

5. CONTRAINDICATIONS

Do not use in eggs or in 1-day-old chickens coming from broiler breeder flocks not vaccinated according to an IBD immunisation program.
Do not use in 1-day-old chickens hatched from eggs vaccinated in-ovo with Cevac Transmune.

6. ADVERSE REACTIONS

In vaccinated chickens, mild to moderate lymphocyte depletion is very commonly observed after the vaccine take, 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.

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 and embryonated chicken eggs

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

Use by the in-ovo or the subcutaneous route:
0.05 ml of Cevac Transmune should be injected into the embryonated egg on the 18th day of embryonation.
or
0.1 ml of Cevac Transmune 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 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 Cevac Transmune, 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:

Cevac Transmune	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	1200 ml
8 x 4,000 doses	1600 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:

Cevac Transmune	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	1200 ml
4 x 4,000 doses	1600 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 PERIOD(S)

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 WARNING(S)

Special precautions for use in animals
Vaccinate healthy animals only.

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 IBD.
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.

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 Cevac Transmune 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 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 the case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

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.

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 (IBD) 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
5x4000 doses	5x4000 doses	1000 ml
6x4000 doses	6x4000 doses	1200 ml
8x4000 doses	8x4000 doses	1600 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
4000 + 1000 doses	4000 + 1000 doses	1000 ml
3 x 2000 doses	3 x 2000 doses	1200 ml
2 x 4000 doses	2 x 4000 doses	1600 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 (symptoms, emergency procedures, antidotes):
No adverse reactions were observed other than stated in relevant section, when a 10-fold overdose was administered.

Incompatibilities:
Do not mix with any other veterinary medicinal product, except Vectormune ND and the solvents 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

September 2022

15. OTHER INFORMATION

Pack sizes of lyophilisate: 2000, 2500, 4000, 5000, 8000 doses, 1 or 20 bottles 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, 1000 ml, 1 or 5 polyolefin based plastic bags in a cardboard box
Pack sizes of solvent (Cevac Solvent Poultry): 200, 400, 800, 1000, 1200, 1600 ml polyvinylchloride bag 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.

For animal treatment only.

To be supplied only on veterinary prescription.

Approved 27 September 2022