

ANNEX I
SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vectormune FP ILT + AE lyophilisate and solvent for suspension for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose (0.01 ml) contains:

Active substances:

Fowlpox virus, strain rFP-LT, expressing fusion protein gene and encapsidation protein gene of avian infectious laryngotracheitis virus, Live 2.7 to 4.5 log₁₀ TCID₅₀*

Avian encephalomyelitis virus, strain Calnek 1143, Live 2.7 to 4.5 log₁₀ EID₅₀**

* 50% Tissue Culture Infective Dose

** 50% Egg Infective Dose

Excipients:

Qualitative composition of excipients and other constituents
Lyophilisate:
Dipotassium phosphate (E340(ii))
Gelatin
Lactose
Potassium dihydrogen phosphate (E340(i))
Sorbitol (E420)
Sucrose
Tryptose phosphate broth
Water for injections
Solvent:
Glycerol (E422)
Patent blue V (E131)
Water for injections

Lyophilisate: whitish-brownish.

Solvent: clear, blue liquid.

3. CLINICAL INFORMATION

3.1 Target species

Chickens.

3.2 Indications for use for each target species

For active immunisation of chickens of 8 to 13 weeks of age in order to reduce the skin lesions due to fowlpox, to reduce the clinical signs and tracheal lesions due to avian infectious laryngotracheitis and to prevent egg production losses due to avian encephalomyelitis.

Onset of immunity:

Fowlpox and avian infectious laryngotracheitis: 3 weeks after vaccination.

Avian encephalomyelitis: 20 weeks after vaccination.

Duration of immunity:

Fowlpox: 34 weeks after vaccination.

Avian infectious laryngotracheitis and avian encephalomyelitis: 57 weeks after vaccination.

3.3 Contraindications

None.

3.4 Special warnings

Vaccinate healthy animals only.

3.5 Special precautions for use

Special precautions for safe use in the target species:

The avian encephalomyelitis virus vaccine strain can spread to unvaccinated chickens. Special precautions should be taken to avoid spreading of the vaccine strain to unvaccinated chickens.

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

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

Chickens:

Very common (>1 animal / 10 animals treated):	Application site swelling ¹ , Application site scab ¹
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¹Small, typical of fowlpox vaccine, should disappear within 14 days after vaccination.

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

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

Wing-web-stab use.

The vaccine is to be administered once from 8 weeks of age and not later than 4 weeks before the onset of lay.

The injection volume is 0.01 ml (10 µl).

The vaccine is delivered by transfixion of inner side of the wing web using the two pronged-applicator supplied with the product. The applicator is inserted from beneath through the wing web and care should be taken to push the feathers aside so as to avoid damaging the blood vessels.

The wing web should be slightly stretched.

Recommended dilutions for administration:

Number of vaccine ampoules	Volume of solvent to be used	Volume of one dose
1x1000 doses	10 ml	0.01 ml
1x2000 doses	20 ml	0.01 ml

Preparation of vaccine suspension for injection:

1. Using a sterile syringe fitted with at least a 20-18 gauge needle, withdraw 4 to 5 ml of solvent from the solvent vial and inject into the vial containing the lyophilisate (freeze-dried vaccine). Swirl gently until the lyophilisate has dissolved.
2. Draw up all the reconstituted vaccine suspension into the syringe and inject into the solvent vial.
3. Then take 4-5 ml of the diluted vaccine suspension from the solvent vial, use it to rinse the vaccine vial and transfer it back into the solvent vial.

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

Ten times the maximum dose was shown to be safe.

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

Any person intending to manufacture, import, possess, distribute, sell, supply and use this veterinary medicinal product must first consult the relevant Member State's competent authority on the current vaccination policies, as these activities may be prohibited in a Member State on the whole or part of its territory pursuant to national legislation.

3.12 Withdrawal periods

Zero days.

4. IMMUNOLOGICAL INFORMATION

4.1 ATCvet code: QI01AD

The vaccine is a live recombinant fowlpox virus expressing the membrane fusion protein and the encapsidation protein of avian infectious laryngotracheitis virus and a live avian encephalomyelitis virus. The vaccine induces active immunity against fowlpox, avian infectious laryngotracheitis and avian encephalomyelitis viruses.

For avian encephalomyelitis, serological data suggest that the maximum seroconversion rate is reached between 4 and 7 weeks after vaccination and is maintained until 57 weeks after vaccination.

For fowl pox, increased speed of cicatrisation is observed until 49 weeks after vaccination.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product except the solvent supplied for use with the veterinary medicinal product.

5.2 Shelf life

Shelf life of the lyophilisate as packaged for sale: 21 months.

Shelf life of the solvent as packaged for sale: 3 years.

Shelf life after reconstitution according to directions: 2 hours.

5.3 Special precautions for storage

Store and transport refrigerated (2 °C – 8 °C).

5.4 Nature and composition of immediate packaging

Lyophilisate:

Type I glass vial containing 1000 or 2000 doses of vaccine.

Solvent (Cevac Solvent Wingweb):

Type I glass vial containing 10 ml (1000 doses) or 20 ml (2000 doses) of solvent.

Presentations:

Cardboard box of 1 vial of 1000 doses of vaccine, 1 vial of 10 ml of solvent and 1 pronged applicator.

Cardboard box of 1 vial of 2000 doses of vaccine, 1 vial of 20 ml of solvent and 1 pronged applicator.

Cardboard box of 5 vials of 1000 doses of vaccine + cardboard box of 5 vials of 10 ml of solvent and 5 pronged applicators.

Cardboard box of 5 vials of 2000 doses of vaccine + cardboard box of 5 vials of 20 ml of solvent and 5 pronged applicators.

Cardboard box of 10 vials of 1000 doses of vaccine + cardboard box of 10 vials of 10 ml of solvent and 10 pronged applicators.

Cardboard box of 10 vials of 2000 doses of vaccine + cardboard box of 10 vials of 20 ml of solvent and 10 pronged applicators.

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-Phylaxia Co. Ltd.

7. MARKETING AUTHORISATION NUMBER(S)

EU/2/20/250/001-006

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 24/04/2020.

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

{MM/YYYY}

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 \(https://medicines.health.europa.eu/veterinary\)](https://medicines.health.europa.eu/veterinary).

ANNEX II

OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

None.

ANNEX III
LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

BOX (lyophilisate + solvent + applicators)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vectormune FP ILT + AE lyophilisate and solvent for suspension for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each dose (0.01 ml) contains:

rFPLT virus 2.7 to 4.5 log₁₀ TCID₅₀

AE virus 2.7 to 4.5 log₁₀ EID₅₀

3. PACKAGE SIZE

1x{1000 doses + 10 ml solvent + 1 pronged applicator}

1x{2000 doses + 20 ml solvent + 1 pronged applicator}

4. TARGET SPECIES

Chickens

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Wing-web-stab use.

7. WITHDRAWAL PERIODS

Withdrawal period: Zero days.

8. EXPIRY DATE

Exp. {mm/yyyy}

Once reconstituted use within 2 hours.

9. SPECIAL STORAGE PRECAUTIONS

Store and transport refrigerated.

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-Phylaxia Co. Ltd.

14. MARKETING AUTHORISATION NUMBERS

EU/2/20/250/001

EU/2/20/250/002

15. BATCH NUMBER

Lot {number} (*of the lyophilisate + solvent*)

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

BOX (lyophilisate)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vectormune FP ILT + AE lyophilisate and solvent for suspension for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each dose (0.01 ml) contains:

rFPLT virus 2.7 to 4.5 log₁₀ TCID₅₀
AE virus 2.7 to 4.5 log₁₀ EID₅₀

3. PACKAGE SIZE

5x1000 doses
5x2000 doses
10x1000 doses
10x2000 doses

4. TARGET SPECIES

Chickens

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Wing-web-stab use.

7. WITHDRAWAL PERIODS

Withdrawal period: Zero days.

8. EXPIRY DATE

Exp. {mm/yyyy}

Once reconstituted use within 2 hours.

9. SPECIAL STORAGE PRECAUTIONS

Store and transport refrigerated.

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-Phylaxia Co. Ltd.

14. MARKETING AUTHORISATION NUMBERS

EU/2/20/250/003 (*5x1000 doses*)
EU/2/20/250/004 (*5x2000 doses*)
EU/2/20/250/005 (*10x1000 doses*)
EU/2/20/250/006 (*10x2000 doses*)

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

BOX (solvent + applicators)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cevac Solvent Wingweb

2. STATEMENT OF ACTIVE SUBSTANCES

3. PACKAGE SIZE

5x10 ml solvent + 5 pronged applicators
5x20 ml solvent + 5 pronged applicators
10x10 ml solvent + 10 pronged applicators
10x20 ml solvent + 10 pronged applicators

4. TARGET SPECIES

Chickens

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Wing-web-stab use.

7. WITHDRAWAL PERIODS

Withdrawal period: Zero days.

8. EXPIRY DATE

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

9. SPECIAL STORAGE PRECAUTIONS

Store and transport refrigerated.

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-Phylaxia Co. Ltd.

14. MARKETING AUTHORISATION NUMBERS

EU/2/20/250/003 (5x10 ml)

EU/2/20/250/004 (5x20 ml)

EU/2/20/250/005 (10x10 ml)

EU/2/20/250/006 (10x20 ml)

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

LABEL OF THE LYOPHILISATE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vectormune FP ILT + AE

1000 doses

2000 doses

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

rFPLT

AE

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

LABEL OF THE SOLVENT

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cevac Solvent Wingweb

10 ml

20 ml

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Vectormune FP ILT + AE lyophilisate and solvent for suspension for injection

2. Composition

Each dose (0.01 ml) contains:

Active substances:

Fowlpox virus, strain rFP-LT, expressing fusion protein gene and encapsidation protein gene of avian infectious laryngotracheitis virus, Live	2.7 to 4.5 log ₁₀ TCID ₅₀ *
Avian encephalomyelitis virus, strain Calnek 1143, Live	2.7 to 4.5 log ₁₀ EID ₅₀ **

* 50% Tissue Culture Infective Dose

** 50% Egg Infective Dose

Lyophilisate: whitish-brownish.

Solvent: clear, blue liquid.

3. Target species

Chickens.

4. Indications for use

For active immunisation of chickens of 8 to 13 weeks of age in order to reduce the clinical signs (skin lesions) due to fowlpox, to reduce the clinical signs and tracheal lesions due to avian infectious laryngotracheitis and to prevent egg production losses due to avian encephalomyelitis.

Onset of immunity:

Fowlpox and avian infectious laryngotracheitis: 3 weeks after vaccination.

Avian encephalomyelitis: 20 weeks after vaccination.

Duration of immunity:

Fowlpox: 34 weeks after vaccination.

Avian infectious laryngotracheitis and avian encephalomyelitis: 57 weeks after vaccination.

5. Contraindications

None.

6. Special warnings

Special warnings for each target species:

Vaccinate healthy animals only.

Special precautions for use in animals:

The avian encephalomyelitis virus vaccine strain can spread to unvaccinated chickens. Special precautions should be taken to avoid spreading of the vaccine strain to unvaccinated chickens.

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

In 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 birds in lay or 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:

Ten times the maximum dose was shown to be safe.

Major incompatibilities:

Do not mix with any other veterinary medicinal product except the solvent supplied for use with the veterinary medicinal product.

Special restrictions for use and special conditions for use:

Any person intending to manufacture, import, possess, distribute, sell, supply and use this veterinary medicinal product must first consult the relevant Member State's competent authority on the current vaccination policies, as these activities may be prohibited in a Member State on the whole or part of its territory pursuant to national legislation

7. Adverse events

Chickens:

Very common (>1 animal / 10 animals treated):	Application site swelling ¹ , Application site scab ¹
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¹Small, typical of fowlpox vaccine, should disappear within 14 days after vaccination.

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: {national system details}

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

Wing web-stab use.

The vaccine is to be administered once from 8 weeks of age and not later than 4 weeks before the onset of lay. The injection volume is 0.01 ml (10µl). The vaccine is delivered by transfixion of the inner side of the wing web with the help of a pronged-applicator. The applicator is inserted from beneath through the wing web and care should be taken to push the feathers aside so as to avoid damaging the blood vessels.

The wing web should be slightly stretched.

Proposed dilutions for administration:

Number of vaccine ampoules	Volume of solvent to be used	Volume of one dose
1x1000 doses	10 ml	0.01 ml
1x2000 doses	20 ml	0.01 ml

9. Advice on correct administration

Preparation of vaccine suspension for injection:

1. Using a sterile syringe fitted with at least a 20-18 gauge needle, withdraw 4 to 5 ml of solvent from the solvent vial and inject into the vial containing the lyophilisate (freeze-dried vaccine). Swirl gently until the lyophilisate has dissolved.
2. Draw up the reconstituted vaccine suspension into the syringe and inject into the solvent vial.
3. Then take 4-5 ml of the diluted vaccine suspension from the solvent vial, use it to rinse the vaccine vial and transfer it back into the solvent vial.

10. Withdrawal periods

Zero days.

11. Special storage precautions

Keep out of the sight and reach of children.

Store and transport refrigerated (2 °C – 8 °C).

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 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

EU/2/20/250/001-006

Lyophilisate: Type I glass vial containing, 1000 or 2000 doses of vaccine.

Solvent (Cevac Solvent Wingweb): Type I glass vial containing 10 ml (1000 doses) or 20 ml (2000 doses) of solvent.

Presentations:

Cardboard box of 1 vial of 1000 doses of vaccine, 1 vial of 10 ml of solvent and 1 pronged applicator.
Cardboard box of 1 vial of 2000 doses of vaccine, 1 vial of 20 ml of solvent and 1 pronged applicator.
Cardboard box of 5 vials of 1000 doses of vaccine + cardboard box of 5 vials of 10 ml of solvent and 5 pronged applicators.

Cardboard box of 5 vials of 2000 doses of vaccine + cardboard box of 5 vials of 20 ml of solvent and 5 pronged applicators.

Cardboard box of 10 vials of 1000 doses of vaccine + cardboard box of 10 vials of 10 ml of solvent and 10 pronged applicators.

Cardboard box of 10 vials of 2000 doses of vaccine + cardboard box of 10 vials of 20 ml of solvent and 10 pronged applicators.

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

{MM/YYYY}

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

16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release and contact details to report suspected adverse events:

Ceva-Phylaxia Co. Ltd.
1107 Budapest Szállás u. 5.
Hungary
Email: pharmacovigilance@ceva.com
Phone number: +800 35 22 11 51