ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vectormune HVT-AIV concentrate and solvent for suspension for injection for chickens

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose of the reconstituted vaccine (0.2 ml) contains:

Active substances:
Turkey herpesvirus, strain rHVT/AI-H5 (FC126, cell-associated), expressing haemagglutinin gene of avian influenza virus subtype H5, live: 2,500 - 12,000 PFU[1].

[1] PFU – plaque-forming unit

Excipients:

Qualitative composition of excipients and other constituents
Concentrate:
EMEM
L-glutamine
Sodium bicarbonate
HEPES
Bovine serum
Dimethyl sulfoxide
Water for injections
Solvent:
Sucrose
Casein hydrolysate
Sorbitol
Dipotassium hydrogen phosphate
Potassium dihydrogen phosphate
Phenol red
Water for injections

Concentrate: orange-yellowish semi-transparent frozen suspension.
Solvent: clear, orange to red solution.

3. CLINICAL INFORMATION

3.1 Target species

Chickens.

3.2 Indications for use for each target species

For active immunisation of one-day-old chickens to reduce mortality, clinical signs, and virus excretion due to infection with highly pathogenic avian influenza (HPAI) virus of the H5 sub-type.

Onset of immunity: 2 weeks of age.
Duration of immunity: 19 weeks.

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:

Although no spread was demonstrated between chickens, data from similar vaccines built on the same HVT vector suggest that vaccinated chickens may excrete the vaccine strain up to 46 days following vaccination. During this time, the contact of immunosuppressed and unvaccinated chickens with vaccinated chickens should be avoided. The vaccine strain can spread to turkeys. Safety trials have shown that the excreted vaccine strain is not harmful in turkeys. However, appropriate veterinary and husbandry measures such as cleaning and disinfection procedures should be taken to avoid spread of the vaccine strain to turkeys.

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

Personal protective equipment consisting of protective gloves, spectacles and boots, should be worn when handling the veterinary medicinal product.

Frozen glass ampoules may explode during sudden temperature changes.
Inhalation of the liquid nitrogen is dangerous. Store and use liquid nitrogen only in a dry and well-ventilated place.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Target species: chickens.
None known.

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

For subcutaneous use.
One single injection of 0.2 ml per chick. The vaccine may be injected by an automatic syringe.

Table 1. Overview table for dilution possibilities of different presentations

Vaccine ampoule presentation (Number of vaccine ampoules multiplied by doses needed)	**Solvent presentation (ml)**	**Volume of one dose (ml)**
2 x 1,000	400	0.20
1 x 2,000	400	
4 x 1,000	800	
2 x 2,000	800	
1 x 4,000	800	
4,000 + 1,000	1,000	
6 x 1,000	1,200	
3 x 2,000	1,200	
4 x 2,000	1,600	
2 x 4,000	1,600	

The usual aseptic precautions should be applied to administration procedure.
Be familiar with all safety and precautionary measures for handling liquid nitrogen in order to prevent personal injury.

Preparation of vaccine suspension for injection:

1. After matching the dose size of the vaccine ampoule presentation with the solvent bag size, quickly remove the exact number of ampoules needed from the liquid nitrogen container.
2. Draw up 2 ml of solvent into a 5 ml syringe.
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 5 ml sterile syringe already containing 2 ml of solvent with a needle of at least 18-gauge diameter.
6. Transfer the suspension into the solvent bag. The diluted vaccine prepared as described is mixed by gentle agitation.
7. Withdraw a portion of the diluted vaccine into the syringe to rinse the ampoule. Remove the washing from the ampoule and inject it gently into the solvent bag. Repeat one or two times.
8. The diluted vaccine prepared as described is mixed by gentle agitation so as to be ready for use.
9. It should be ensured that the vaccine suspension is mixed regularly in a gentle way during the vaccination session to guarantee that the vaccine suspension remains homogenous.

Repeat the operations in point 2 to 7 for the appropriate number of ampoules to be thawed.
Use the vaccine immediately, slowly mix regularly to ensure uniform suspension of cells and use within a period not exceeding 2 hours.

The reconstituted vaccine is a clear, red-coloured suspension for injection.

Discard any ampoules that have been accidentally thawed.
Do not re-freeze under any circumstances.
Do not re-use open containers of reconstituted vaccine.

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

No symptoms were observed after the administration of a maximum 4-fold dose of vaccine.

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 induces active immunity against highly pathogenic avian influenza H5 and Marek's disease in chickens.

The vaccine contains a cell-associated, live recombinant herpesvirus of turkey (HVT, Marek's disease virus serotype 3), which is genetically modified to express the haemagglutinin 5 (HA) of HPAIV.

As this vaccine elicits only antibodies against the H5 protein of HPAIV, the use of appropriate diagnostic tools allows for Differentiating Infected from Vaccinated Animals (DIVA).

The duration of immunity is 19 weeks after vaccination, demonstrated for clade 2.2.1 and supported by bibliographic data.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product except the solvent recommended for use (Cevac Solvent Poultry) with the veterinary medicinal product.

5.2 Shelf life

Shelf life of the concentrate 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.

5.3 Special precautions for storage

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

Concentrate

One type I glass ampoule containing 1,000, 2,000 or 4,000 doses of the vaccine.
Ampoules are stored on canes with tags showing the batch number and doses.
The canes with ampoules are stored in a liquid nitrogen container.

Solvent

Polyvinylchloride bag containing 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 product 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)

EU/2/25/335/001-003

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 28/03/2025

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

EXCEPTIONAL CIRCUMSTANCES:

Marketing authorisation in exceptional circumstances and therefore assessment based on customised requirements for documentation. Only a limited assessment of quality, safety or efficacy has been conducted due to the lack of comprehensive quality, safety or efficacy data.

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 II

OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

SPECIFIC OBLIGATION TO COMPLETE POST-AUTHORISATION MEASURES FOR THE MARKETING AUTHORISATION IN EXCEPTIONAL CIRCUMSTANCES

This being an approval in exceptional circumstances and pursuant to Article 25 of Regulation (EU) 2019/6, the MAH shall conduct, within the stated timeframe, the following measures:

Description	**Due date**
Duration of immunity studies: results of the challenge studies that have been initiated by the applicant should be provided as soon as available.	December 2025
Complete stability data for one batch controlled in Europe including results for appearance and sterility at the end of the observation period should be provided.	November 2026

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Ampoule and tag of 1 000, 2 000 or 4 000 doses

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vectormune HVT-AIV

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

rHVT/AIV H5

3. BATCH NUMBER

Lot {number}

1000 doses
2000 doses
4000 doses

4. EXPIRY DATE

Exp. {mm/yyyy}

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

Solvent bags of 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
Ceva Santé Animale

9. BATCH NUMBER

Lot {number}

400 ml
800 ml
1000 ml
1200 ml
1600 ml

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Vectormune HVT-AIV concentrate and solvent for suspension for injection for chickens

2. Composition

Each dose of the reconstituted vaccine (0.2 ml) contains:

Active substances:
Turkey herpesvirus, strain rHVT/AI-H5 (FC126, cell-associated), expressing haemagglutinin gene of avian influenza subtype H5 virus, Live: 2,500 - 12,000 PFU[1].

[1] PFU – plaque-forming unit

Concentrate: orange-yellowish semi-transparent frozen suspension.
Solvent: clear, orange to red solution.

3. Target species

Chickens.

4. Indications for use

For active immunisation of one-day-old chickens to reduce mortality, clinical signs and virus excretion due to infection with highly pathogenic avian influenza (HPAI) virus of the H5 sub-type.

Onset of immunity: 2 weeks of age
Duration of immunity: 19 weeks

5. Contraindications

None.

6. Special warnings

Special warnings:

Vaccinate healthy animals only.

Special precautions for safe use in the target species:

Although no spread was demonstrated between chickens, data from similar vaccines built on the same HVT vector suggest that vaccinated chickens may excrete the vaccine strain up to 46 days following vaccination. During this time, the contact of immunosuppressed and unvaccinated chickens with vaccinated chickens should be avoided. The vaccine strain can spread to turkeys. Safety trials have shown that the excreted vaccine strain is not harmful in turkeys. However, appropriate veterinary and husbandry measures such as cleaning and disinfection procedures should be taken to avoid spread of the vaccine strain to turkeys.

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

Personal protective equipment consisting of protective gloves, spectacles and boots, should be worn when handling the veterinary medicinal product.

Frozen glass ampoules may explode during sudden temperature changes.
Inhalation of the liquid nitrogen is dangerous. Store and use liquid nitrogen only in a dry and well-ventilated place.

Special precautions for the protection of the environment:

Not applicable.

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 symptoms were observed after the administration of an overdose.

Major incompatibilities:

Do not mix with any other veterinary medicinal product except the solvent recommended for use (Cevac Solvent Poultry) with the veterinary medicinal product.

7. Adverse events

None.

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

For subcutaneous use.
One single injection of 0.2 ml per chick. The vaccine may be injected by an automatic syringe.

Overview table for dilution possibilities of different presentations:

Vaccine ampoule presentation (Number of vaccine ampoules multiplied by doses needed)	Solvent presentation (ml)	Volume of one dose (ml)
2 x 1,000	400	0.20
1 x 2,000	400	
4 x 1,000	800	
2 x 2,000	800	
1 x 4,000	800	
4,000 + 1,000	1,000	
6 x 1,000	1,200	
3 x 2,000	1,200	
4 x 2,000	1,600	
2 x 4,000	1,600	

9. Advice on correct administration

The usual aseptic precautions should be applied to administration procedure.
Be familiar with all safety and precautionary measures for handling liquid nitrogen in order to prevent personal injury.

Preparation of vaccine suspension for injection:

1. After matching the dose size of the vaccine ampoule presentation with the solvent bag size, quickly remove the exact number of ampoules needed from the liquid nitrogen container.
2. Draw up 2 ml of solvent into a 5 ml syringe.
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 5 ml sterile syringe already containing 2 ml of solvent with a needle of at least 18-gauge diameter.
6. Transfer the suspension into the solvent bag. The diluted vaccine prepared as described is mixed by gentle agitation.
7. Withdraw a portion of the diluted vaccine into the syringe to rinse the ampoule. Remove the washing from the ampoule and inject it gently into the solvent bag. Repeat one or two times.
8. The diluted vaccine prepared as described is mixed by gentle agitation so as to be ready for use.
9. It should be ensured that the vaccine suspension is mixed regularly in a gentle way during the vaccination session to guarantee that the vaccine suspension remains homogenous.

Repeat the operations in point 2 to 7 for the appropriate number of ampoules to be thawed.
Use the vaccine immediately, slowly mix regularly to ensure uniform suspension of cells and use within a period not exceeding 2 hours.

The reconstituted vaccine is a clear, red coloured suspension for injection.

Discard any ampoules that have been accidentally thawed.
Do not re-freeze under any circumstances.
Do not re-use open containers of diluted vaccine.

10. Withdrawal periods

Zero days.

11. Special storage precautions

Keep out of the sight and reach of children.

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 ampoule after Exp. 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/2/25/335/001-003

Concentrate: 2 ml glass ampoule, containing 1,000, 2,000 or 4,000 doses.

Solvent: 400 ml, 800 ml, 1000 ml, 1200 ml and 1600 ml in plastic bag in individual over-pouch.

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

09/2025

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 reactions:

Ceva Santé Animale
8 rue de Logrono
33500 Libourne
France
Phone number: +800 35 22 11 51
Email: pharmacovigilance@ceva.com

Manufacturer responsible for batch release:
Ceva-Phylaxia Co. Ltd.
1107 Budapest, Szállás u. 5.
Hungary

17. Other information

The vaccine induces active immunity against highly pathogenic avian influenza H5 and Marek's disease in chickens. Antibodies against MDV and AIV can therefore be detected after vaccination.

As this vaccine elicits only antibodies against the H5 protein of HPAIV, the use of appropriate diagnostic tools allows for Differentiating Infected from Vaccinated Animals (DIVA).

The duration of immunity is 19 weeks after vaccination, demonstrated for clade 2.2.1 and supported by bibliographic data.