ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

EVANOVO suspension and solvent for suspension for injection for chickens

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose (0.006 ml) of undiluted vaccine contains:

Active substances:

Eimeria acervulina, strain 044	598 - 809*
Eimeria maxima, strain 013	352 - 476*
Eimeria praecox, strain 007	235 - 317*
Eimeria tenella, strain 004	221 - 299*

* Number of sporulated oocysts derived from precocious attenuated lines of coccidia, according to *in vitro* procedures of the manufacturer at the time of blending.

Excipients:

Qualitative composition of excipients and other constituents
EVANOVO suspension:
Disodium phosphate dodecahydrate
Polysorbate 80
Potassium chloride
Potassium dihydrogen phosphate
Purified water
Sodium chloride
HIPRAHATCH solvent, for poultry vaccines:
Disodium phosphate dodecahydrate
Potassium chloride
Potassium dihydrogen phosphate
Sodium chloride
Water for injections

Suspension: white turbid suspension.
Solvent: clear colourless solution.

3. CLINICAL INFORMATION

3.1 Target species

Chicken embryonated eggs.

3.2 Indications for use for each target species

For the active immunisation of chickens to reduce clinical signs (diarrhoea), intestinal lesions and oocysts output associated with coccidiosis caused by *Eimeria acervulina, Eimeria maxima* and *Eimeria praecox,* and for the reduction of clinical signs, intestinal lesions and oocysts output associated with coccidiosis caused by *Eimeria tenella*.

Onset of immunity: 21 days of age.

Duration of immunity: 63 days of age in an environment that permits oocysts recycling.

3.3 Contraindications

None.

3.4 Special warnings

The vaccine will not protect species other than chickens against coccidiosis.

Vaccinate healthy embryos only.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Chickens must be strictly floor-reared in the first 3 weeks after vaccination.

In order to reduce field infections, it is recommended that all litter should be removed and facilities and related equipment in contact with vaccinated chickens should be cleaned between production cycles.

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

Wash and disinfect hands and equipment after use.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

None known.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See section ”Contact details” of the package leaflet.

3.7 Use during pregnancy, lactation or lay

Not applicable.

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 with GUMBOHATCH prior to use and administered simultaneously *in ovo.* The product information of GUMBOHATCH should be consulted before administration of the mixed products.

The mixed administration of GUMBOHATCH and EVANOVO should only be used when vaccinating 18-day-old embryonated eggs.

For mixed use, the onset and duration of immunity of the *Eimeria* species included in the EVANOVO vaccine have been demonstrated to be equivalent to those determined for EVANOVO when used alone.

No information is available on the safety and efficacy of this immunological veterinary medicinal product when used with any other veterinary medicinal product except the product mentioned above. A decision to use this immunological veterinary medicinal product before or after any other veterinary medicinal product therefore needs to be made on a case by case basis.

No anticoccidial substances or other agents having anticoccidial activity via feed or water should be used for at least 3 weeks following the hatching of chickens from vaccinated eggs with this product otherwise the correct replication of the vaccine oocysts, and consequently the development of a solid immunity, could be hindered. Additionally, the duration of immunity depends on an environment that permits recycling of oocysts, therefore a decision to use any anticoccidial substances in the period after 3 weeks of age should be made taking into account the potential negative impact on the duration of immunity of this product.

3.9 Administration routes and dosage

In ovo administration.

Vaccination schedule:
Administer one single injection of 0.05 ml or 0.1 ml of the diluted vaccine suspension into each chicken egg at 18 days of embryonation.

Method of administration:
An automated egg injection machine can be used. *In ovo* equipment should be previously calibrated to ensure that a 0.05 ml or 0.1 ml dose is applied. The instructions for the calibration and use of the equipment should be strictly followed, in order to deliver the appropriate dose in the amnion of the embryonated egg.

For the dilution and administration of the vaccine, use sterile equipment free from any residues of chemical disinfectants.

Prepare the required volume of the vaccine as per the examples provided in the tables below, showing different dilution possibilities, according to different presentations:

Dilutions for *in ovo* administration (0.05 ml per dose):

Number and content of vaccine vials	HIPRAHATCH solvent volume to be used	Volume of solvent to be withdrawn before vaccine dilution
4 x 1 000 doses	200 ml	24 ml
2 x 2 000 doses	200 ml	24 ml
4 x 2 000 doses	400 ml	48 ml
1 x 4 000 doses	200 ml	24 ml
2 x 4 000 doses	400 ml	48 ml
4 x 4 000 doses	800 ml	96 ml
5 x 4 000 doses	1 000 ml	120 ml
2 x 5 000 doses	500 ml	60 ml
4 x 5 000 doses	1 000 ml	120 ml
1 x 8 000 doses	400 ml	48 ml
2 x 8 000 doses	800 ml	96 ml
1 x 10 000 doses	500 ml	60 ml
2 x 10 000 doses	1 000 ml	120 ml

Dilutions for *in ovo* administration (0.1 ml per dose):

Number and content of vaccine vials	HIPRAHATCH solvent volume to be used	Volume of solvent to be withdrawn before vaccine dilution
2 x 1 000 doses	200 ml	12 ml
4 x 1 000 doses	400 ml	24 ml
1 x 2 000 doses	200 ml	12 ml
2 x 2 000 doses	400 ml	24 ml
4 x 2 000 doses	800 ml	48 ml
1 x 4 000 doses	400 ml	24 ml
2 x 4 000 doses	800 ml	48 ml
1 x 5 000 doses	500 ml	30 ml
2 x 5 000 doses	1 000 ml	60 ml
1 x 8 000 doses	800 ml	48 ml
1 x 10 000 doses	1 000 ml	60 ml

Dilution of the vaccine:
1. Withdraw from the HIPRAHATCH solvent bag the same millilitres that are going to be injected of vaccine (EVANOVO), as stated in the example tables above.
2. Shake the vaccine vial/s and inject the content of it/them into the HIPRAHATCH solvent bag. Mix the contents of the bag by gentle agitation until the contents are completely diluted.
3. The diluted vaccine is a white suspension, which should be used within 10 hours after dilution. Mix the bag by gentle agitation every 30 minutes during vaccination.

The vaccine must be injected into the amniotic sac of 18-day-old embryonated chicken eggs.

For simultaneous use with GUMBOHATCH, the mixed administration of EVANOVO and GUMBOHATCH should only be used when vaccinating *in ovo* 18-day-old embryonated eggs.

The following instructions should be used:

1.1 Taking into account the HIPRAHATCH solvent bag volume, prepare the EVANOVO vaccine as described above.
1.2 Once the EVANOVO vaccine has been prepared, consider the bag volume to prepare enough GUMBOHATCH doses for the bag volume.
1.3 In each GUMBOHATCH vial to be used, insert 4 ml of the EVANOVO diluted vaccinal suspension prepared in section 1.1.
1.4 Once the lyophilized tablet is properly resuspended, introduce the volumes of the different GUMBOHATCH vials into the vaccinal bag.
1.5 Homogenize by moving the bag volume with the hands until having an even homogenate solution.
1.6 Vaccinate using the vaccinal bag with the mixed vaccines within a period of 2 hours via *in ovo*. Mix the bag by gentle agitation every 30 minutes during vaccination.

Prepare the required volume of each vaccine as per the examples provided in the table below, showing different mixing possibilities, according to different presentations **for *in ovo* administration (0.05 ml per dose):**

GUMBOHATCH (Number and content of vaccine vials)	EVANOVO (Number and content of vaccine vials)	HIPRAHATCH solvent volume to be used
4 x 1 000 doses	4 x 1 000 doses	200 ml
2 x 2 000 doses	2 x 2 000 doses	200 ml
4 x 2 000 doses	4 x 2 000 doses	400 ml

1 x 4 000 doses	1 x 4 000 doses	200 ml
2 x 4 000 doses	4 x 2 000 doses	400 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
2 x 5 000 doses	2 x 5 000 doses	500 ml
8 x 2 500 doses	4 x 5 000 doses	1 000 ml
2 x 4 000 doses	1 x 8 000 doses	400 ml
1 x 8 000 doses	1 x 8 000 doses	400 ml
4 x 4 000 doses	2 x 8 000 doses	800 ml
2 x 8 000 doses	2 x 8 000 doses	800 ml
4 x 2 500 doses	1 x 10 000 doses	500 ml
1 x 10 000 doses	1 x 10 000 doses	500 ml
5 x 4 000 doses	2 x 10 000 doses	1 000 ml
4 x 5 000 doses	2 x 10 000 doses	1 000 ml
2 x 10 000 doses	2 x 10 000 doses	1 000 ml

The vaccine should not be used in case its appearance is different from a white turbid suspension.

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

No adverse reactions were observed after the administration of a 10-fold overdose.

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: QI01AN01.

To stimulate active immunity against coccidiosis caused by *Eimeria acervulina*, *Eimeria maxima, Eimeria praecox* and *Eimeria tenella.*

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 and except those mentioned in section 3.8 above.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 1 year.
Shelf life of the HIPRAHATCH solvent as packaged for sale: 3 years.
Shelf life after dilution according to directions: 10 hours.
Shelf life after mixing with GUMBOHATCH: 2 hours.

5.3 Special precautions for storage

EVANOVO suspension:
Store and transport refrigerated (2 ºC - 8 ºC).
Do not freeze.
Protect from light.

HIPRAHATCH solvent, for poultry vaccines:
Do not store above 25 ºC.

5.4 Nature and composition of immediate packaging

EVANOVO suspension:
Type I colourless glass vials containing 6 ml, 12 ml, 24 ml, 30 ml, 48 ml or 60 ml of suspension (1 000, 2 000, 4 000, 5 000, 8 000 and 10 000 doses) closed with type I polymeric elastomer closures and aluminium caps.

HIPRAHATCH solvent, for poultry vaccines:
Polypropylene bags containing 200 ml, 400 ml, 500 ml, 800 ml or 1 000 ml.

Package sizes:
Cardboard box with one vial of EVANOVO suspension containing 6 ml (1 000 doses).
Cardboard box with one vial of EVANOVO suspension containing 12 ml (2 000 doses).
Cardboard box with one vial of EVANOVO suspension containing 24 ml (4 000 doses).
Cardboard box with one vial of EVANOVO suspension containing 30 ml (5 000 doses).
Cardboard box with one vial of EVANOVO suspension containing 48 ml (8 000 doses).
Cardboard box with one vial of EVANOVO suspension containing 60 ml (10 000 doses).

Cardboard box with 10 bags containing 200 ml of HIPRAHATCH solvent.
Cardboard box with 10 bags containing 400 ml of HIPRAHATCH solvent.
Cardboard box with 10 bags containing 500 ml of HIPRAHATCH solvent.
Cardboard box with 10 bags containing 800 ml of HIPRAHATCH solvent.
Cardboard box with 10 bags containing 1 000 ml of HIPRAHATCH solvent.

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

LABORATORIOS HIPRA, S.A.

7. MARKETING AUTHORISATION NUMBER(S)

EU/2/22/284/001-006

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 27/07/2022

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*).

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

Cardboard boxes

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

EVANOVO suspension and solvent for suspension for injection for chickens

2. STATEMENT OF ACTIVE SUBSTANCES

Each dose (0.006 ml) of undiluted vaccine contains:

Eimeria acervulina, strain 044	598 – 809
Eimeria maxima, strain 013	352 – 476
Eimeria praecox, strain 007	235 – 317
Eimeria tenella, strain 004	221 – 299

3. PACKAGE SIZE

1 000 doses (6 ml)
2 000 doses (12 ml)
4 000 doses (24 ml)
5 000 doses (30 ml)
8 000 doses (48 ml)
10 000 doses (60 ml)

4. TARGET SPECIES

Chicken embryonated eggs.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

In ovo administration.
To be mixed with HIPRAHATCH solvent.

7. WITHDRAWAL PERIODS

Withdrawal period: zero days.

8. EXPIRY DATE

Exp. {mm/yyyy}
Once diluted use within 10 hours.

9. SPECIAL STORAGE PRECAUTIONS

Store and transport refrigerated.
Do not freeze.
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

LABORATORIOS HIPRA, S.A.

14. MARKETING AUTHORISATION NUMBERS

EU/2/22/284/001 (1 000 doses)
EU/2/22/284/002 (2 000 doses)
EU/2/22/284/003 (4 000 doses)
EU/2/22/284/004 (5 000 doses)
EU/2/22/284/005 (10 000 doses)
EU/2/22/284/006 (8 000 doses)

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Vaccine vial of 8 000 or 10 000 doses

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

EVANOVO suspension and solvent for suspension for injection for chickens.

2. STATEMENT OF ACTIVE SUBSTANCES

Each dose (0.006 ml) of undiluted vaccine contains:

Eimeria acervulina, strain 044	598 - 809
Eimeria maxima, strain 013	352 - 476
Eimeria praecox, strain 007	235 - 317
Eimeria tenella, strain 004	221 - 299

3. TARGET SPECIES

Chicken embryonated eggs.

4. ROUTES OF ADMINISTRATION

In ovo administration.
To be mixed with HIPRAHATCH solvent.
Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal period: zero days.

6. EXPIRY DATE

Exp. {mm/yyyy}
Once diluted use within 10 hours.

7. SPECIAL STORAGE PRECAUTIONS

Store and transport refrigerated.
Do not freeze.
Protect from light.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

LABORATORIOS HIPRA, S.A.

9. BATCH NUMBER

Lot {number}

10. CONTENT BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

8 000 doses (48 ml)
10 000 doses (60 ml)

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Vaccine vial of 1 000, 2 000, 4 000 or 5 000 doses

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

EVANOVO suspension and solvent for suspension for injection for chickens.

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Each dose (0.006 ml) of undiluted vaccine contains:

Eimeria acervulina, strain 044	598 - 809
Eimeria maxima, strain 013	352 - 476
Eimeria praecox, strain 007	235 - 317
Eimeria tenella, strain 004	221 - 299

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}
Once diluted use within 10 hours.

5. CONTENT BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

1 000 doses (6 ml)
2 000 doses (12 ml)
4 000 doses (24 ml)
5 000 doses (30 ml)

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard boxes (solvent bags)

1. NAME OF THE SOLVENT

HIPRAHATCH solvent, for poultry vaccines.

2. ROUTE(S) OF ADMINISTRATION

Read the package leaflet supplied with the vaccine vial before use.

3. EXPIRY DATE

Exp. {mm/yyyy}

4. SPECIAL STORAGE PRECAUTIONS

Do not store above 25 °C.

5. NAME OF THE MARKETING AUTHORISATION HOLDER

LABORATORIOS HIPRA, S.A.

6. BATCH NUMBER

Lot {number}

7. PACKAGE SIZE

10 x 200 ml
10 x 400 ml
10 x 500 ml
10 x 800 ml
10 x 1 000 ml

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Solvent bag

1. NAME OF THE SOLVENT

HIPRAHATCH solvent, for poultry vaccines.

2. ROUTE(S) OF ADMINISTRATION

Read the package leaflet supplied with the vaccine vial before use.

3. EXPIRY DATE

Exp.{mm/yyyy}

4. SPECIAL STORAGE PRECAUTIONS

Do not store above 25 ºC.

5. NAME OF THE MARKETING AUTHORISATION HOLDER

LABORATORIOS HIPRA, S.A.

6. BATCH NUMBER

Lot {number}

7. PACKAGE SIZE

200 ml
400 ml
500 ml
800 ml
1 000 ml

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

EVANOVO suspension and solvent for suspension for injection for chickens.

2. Composition

Active substances:
Each dose (0.006 ml) of undiluted vaccine contains:

Eimeria acervulina, strain 044	598 - 809*
Eimeria maxima, strain 013	352 - 476*
Eimeria praecox, strain 007	235 - 317*
Eimeria tenella, strain 004	221 - 299*

* Number of sporulated oocysts derived from precocious attenuated lines of coccidia, according to *in vitro* procedures of the manufacturer at the time of blending.

Suspension: white turbid suspension.
Solvent: clear colourless solution.

3. Target species

Chicken embryonated eggs.

4. Indications for use

For the active immunisation of chickens to reduce clinical signs (diarrhoea), intestinal lesions and oocysts output associated with coccidiosis caused by *Eimeria acervulina, Eimeria maxima* and *Eimeria praecox,* and for the reduction of clinical signs, intestinal lesions and oocysts output associated with coccidiosis caused by *Eimeria tenella*.

Onset of immunity: 21 days of age.

Duration of immunity: 63 days of age in an environment that permits oocysts recycling.

5. Contraindications

None.

6. Special warnings

Special warnings:
The vaccine will not protect species other than chickens against coccidiosis.

Vaccinate healthy embryos only.

Special precautions for safe use in the target species:

Chickens must be strictly floor-reared in the first 3 weeks after vaccination.

In order to reduce field infections, it is recommended that all litter should be removed and facilities and related equipment in contact with vaccinated chickens should be cleaned between production cycles.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Wash and disinfect hands and equipment after use.

Special precautions for the protection of the environment:
Not applicable.

Interaction with other medicinal products and other forms of interaction:
Safety and efficacy data are available which demonstrate that this vaccine can be mixed with GUMBOHATCH prior to use and administered simultaneously *in ovo*. The product information of GUMBOHATCH should be consulted before administration of the mixed products.

The mixed administration of GUMBOHATCH and EVANOVO should only be used when vaccinating 18-day-old embryonated eggs.

For mixed use, the onset and duration of immunity of the *Eimeria* species included in the EVANOVO vaccine have been demonstrated to be equivalent to those determined for EVANOVO when used alone.

No information is available on the safety and efficacy of this immunological veterinary medicinal product when used with any other veterinary medicinal product except the product mentioned above. A decision to use this immunological veterinary medicinal product before or after any other veterinary medicinal product therefore needs to be made on a case by case basis.

No anticoccidial substances or other agents having anticoccidial activity via feed or water should be used for at least 3 weeks following the hatching of chickens from vaccinated eggs with this product otherwise the correct replication of the vaccine oocysts, and consequently the development of a solid immunity, could be hindered. Additionally, the duration of immunity depends on an environment that permits recycling of oocysts, therefore a decision to use any anticoccidial substances in the period after 3 weeks of age should be made taking into account the potential negative impact on the duration of immunity of this product.

Overdose:
No adverse reactions were observed after the administration of a 10-fold overdose.

Major incompatibilities:
Do not mix with any other veterinary medicinal product, except the solvent supplied for use with the veterinary medicinal product.or GUMBOHATCH.

7. Adverse events

None known.

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 or the local representative of 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

In ovo administration.
Administer one single injection of 0.05 ml or 0.1 ml of the diluted vaccine suspension into each chicken egg at 18 days of embryonation.

9. Advice on correct administration

An automated egg injection machine can be used. *In ovo* equipment should be previously calibrated to ensure that a 0.05 ml or 0.1 ml dose is applied. The instructions for the calibration and use of the equipment should be strictly followed, in order to deliver the appropriate dose in the amnion of the embryonated egg.

For the dilution and administration of the vaccine, use sterile equipment free from any residues of chemical disinfectants.

Prepare the required volume of the vaccine as per the examples provided in the tables below, showing different dilution possibilities, according to different presentations:

Dilutions for *in ovo* administration (0.05 ml per dose):

Number and content of vaccine vials	HIPRAHATCH solvent volume to be used	Volume of solvent to be withdrawn before vaccine dilution
4 x 1 000 doses	200 ml	24 ml
2 x 2 000 doses	200 ml	24 ml
4 x 2 000 doses	400 ml	48 ml
1 x 4 000 doses	200 ml	24 ml
2 x 4 000 doses	400 ml	48 ml
4 x 4 000 doses	800 ml	96 ml
5 x 4 000 doses	1 000 ml	120 ml
2 x 5 000 doses	500 ml	60 ml
4 x 5 000 doses	1 000 ml	120 ml
1 x 8 000 doses	400 ml	48 ml
2 x 8 000 doses	800 ml	96 ml
1 x 10 000 doses	500 ml	60 ml
2 x 10 000 doses	1 000 ml	120 ml

Dilutions for *in ovo* administration (0.1 ml per dose):

Number and content of vaccine vials	HIPRAHATCH solvent volume to be used	Volume of solvent to be withdrawn before vaccine dilution
2 x 1 000 doses	200 ml	12 ml
4 x 1 000 doses	400 ml	24 ml
1 x 2 000 doses	200 ml	12 ml
2 x 2 000 doses	400 ml	24 ml
4 x 2 000 doses	800 ml	48 ml
1 x 4 000 doses	400 ml	24 ml
2 x 4 000 doses	800 ml	48 ml
1 x 5 000 doses	500 ml	30 ml
2 x 5 000 doses	1 000 ml	60 ml
1 x 8 000 doses	800 ml	48 ml
1 x 10 000 doses	1 000 ml	60 ml

Dilution of the vaccine:

1. Withdraw from the HIPRAHATCH solvent bag the same millilitres that are going to be injected of vaccine (EVANOVO), as stated in the example tables above.
2. Shake the vaccine vial/s and inject the content of it/them into the HIPRAHATCH solvent bag. Mix the contents of the bag by gentle agitation until the contents are completely diluted.
3. The diluted vaccine is a white suspension, which should be used within 10 hours after dilution. Mix the bag by gentle agitation every 30 minutes during vaccination.

The vaccine must be injected into the amniotic sac of 18-day-old embryonated chicken eggs.

For simultaneous use with GUMBOHATCH, the mixed administration of EVANOVO and GUMBOHATCH should only be used when vaccinating *in ovo* 18-day-old embryonated eggs.

The following instructions should be used:

1.1 Taking into account the HIPRAHATCH solvent bag volume, prepare the EVANOVO vaccine as described above.
1.2 Once the EVANOVO vaccine has been prepared, consider the bag volume to prepare enough GUMBOHATCH doses for the bag volume.
1.3 In each GUMBOHATCH vial to be used, insert 4 ml of the EVANOVO diluted vaccinal suspension prepared in section 1.1.
1.4 Once the lyophilized tablet is properly resuspended, introduce the volumes of the different GUMBOHATCH vials into the vaccinal bag.
1.5 Homogenize by moving the bag volume with the hands until having an even homogenate solution.
1.6 Vaccinate using the vaccinal bag with the mixed vaccines within a period of 2 hours via *in ovo*. Mix the bag by gentle agitation every 30 minutes during vaccination.

Prepare the required volume of each vaccine as per the examples provided in the table below, showing different mixing possibilities, according to different presentations **for *in ovo* administration (0.05 ml per dose):**

GUMBOHATCH (Number and content of vaccine vials)	**EVANOVO (Number and content of vaccine vials)**	**HIPRAHATCH solvent volume to be used**
4 x 1 000 doses	4 x 1 000 doses	200 ml
2 x 2 000 doses	2 x 2 000 doses	200 ml
4 x 2 000 doses	4 x 2 000 doses	400 ml
1 x 4 000 doses	1 x 4 000 doses	200 ml
2 x 4 000 doses	4 x 2 000 doses	400 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
2 x 5 000 doses	2 x 5 000 doses	500 ml
8 x 2 500 doses	4 x 5 000 doses	1 000 ml
2 x 4 000 doses	1 x 8 000 doses	400 ml
1 x 8 000 doses	1 x 8 000 doses	400 ml
4 x 4 000 doses	2 x 8 000 doses	800 ml
2 x 8 000 doses	2 x 8 000 doses	800 ml
4 x 2 500 doses	1 x 10 000 doses	500 ml
1 x 10 000 doses	1 x 10 000 doses	500 ml
5 x 4 000 doses	2 x 10 000 doses	1 000 ml
4 x 5 000 doses	2 x 10 000 doses	1 000 ml
2 x 10 000 doses	2 x 10 000 doses	1 000 ml

The vaccine should not be used in case its appearance is different from a white turbid suspension.

10. Withdrawal periods

Zero days.

11. Special storage precautions

Keep out of the sight and reach of children.

EVANOVO suspension:
Store and transport refrigerated (2 ºC - 8 ºC).
Do not freeze.
Protect from light.

HIPRAHATCH solvent, for poultry vaccines:
Do not store above 25 ºC.

Shelf life after dilution according to directions: 10 hours.
Shelf life after mixing with GUMBOHATCH: 2 hours.

Do not use this veterinary medicinal product after the expiry date, which is stated on the label and the carton. The expiry date refers to the last day of that month.

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.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Marketing authorisation number: EU/2/22/284/001-006

Pack sizes:
Cardboard box with one vial of EVANOVO suspension containing 6 ml (1 000 doses).
Cardboard box with one vial of EVANOVO suspension containing 12 ml (2 000 doses).
Cardboard box with one vial of EVANOVO suspension containing 24 ml (4 000 doses).
Cardboard box with one vial of EVANOVO suspension containing 30 ml (5 000 doses).
Cardboard box with one vial of EVANOVO suspension containing 48 ml (8 000 doses).
Cardboard box with one vial of EVANOVO suspension containing 60 ml (10 000 doses).

Cardboard box with 10 bags containing 200 ml of HIPRAHATCH solvent.

Cardboard box with 10 bags containing 400 ml of HIPRAHATCH solvent.
Cardboard box with 10 bags containing 500 ml of HIPRAHATCH solvent.
Cardboard box with 10 bags containing 800 ml of HIPRAHATCH solvent.
Cardboard box with 10 bags containing 1 000 ml of HIPRAHATCH solvent.

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*).

16. Contact details

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

LABORATORIOS HIPRA, S.A.
Avda. La Selva 135
17170 Amer (Girona) SPAIN
Tel: +34 972 43 06 60

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

Local representatives and contact details to report suspected adverse reactions:

België/Belgique/Belgien HIPRA BENELUX NV Nieuwewandeling 62 9000 Gent BELGIUM Tél/Tel: +32 09 2964464	**Lietuva** LABORATORIOS HIPRA, S.A. Avda. La Selva 135 17170 Amer (Girona) ISPANIJA Tel: +34 972 43 06 60
Република България LABORATORIOS HIPRA, S.A. Avda. La Selva 135 17170 Amer (Girona) ИСПАНИЯ Тел: +34 972 43 06 60	**Luxembourg/Luxemburg** HIPRA BENELUX NV Nieuwewandeling 62 9000 Gent BELGIUM Tél/Tel: +32 09 2964464
Česká republika HIPRA SLOVENSKO, s.r.o. Zochova 5, 811 03 Bratislava, SLOVENSKO Tel: +421 02 32 335 223	**Magyarország** LABORATORIOS HIPRA, S.A. Avda. La Selva 135 17170 Amer (Girona) SPANYOLORSZÁG Tel: +34 972 43 06 60

Danmark LABORATORIOS HIPRA, S.A. Avda. La Selva 135 17170 Amer (Girona) SPANIEN Tel: +34 972 43 06 60	**Malta** LABORATORIOS HIPRA, S.A. Avda. La Selva 135 17170 Amer (Girona) SPANJA Tel: +34 972 43 06 60
Deutschland HIPRA DEUTSCHLAND GmbH Am Wehrhahn 28-30 40211 Düsseldorf Deutschland Tel: +49 211 698236 – 0	**Nederland** HIPRA BENELUX NV Nieuwewandeling 62 9000 Gent BELGIUM Tel: +32 09 2964464
Eesti LABORATORIOS HIPRA, S.A. Avda. La Selva 135 17170 Amer (Girona) HISPAANIA Tel: +34 972 43 06 60	**Norge** LABORATORIOS HIPRA, S.A. Avda. La Selva 135 17170 Amer (Girona) SPANIA Tlf: +34 972 43 06 60
Ελλάδα HIPRA ΕΛΛΑΣ Α.Ε. Λεωφ. Αθηνών 80 & Μηριόνου 2-4, 104 41 Κολωνός - ΑΘΗΝΑ - ΕΛΛΑΣ Τηλ: +30 210 4978660	**Österreich** HIPRA DEUTSCHLAND GmbH Am Wehrhahn 28-30 40211 Düsseldorf Deutschland Tel: +49 211 698236 – 0
España LABORATORIOS HIPRA, S.A. Avda. La Selva 135 17170 Amer (Girona) ESPAÑA Tel: +34 972 43 06 60	**Polska** HIPRA POLSKA Sp.z.o.o. Ul.Wincentego Rzymowskiego 31 02-697 Warszawa POLSKA Tel: +48 22 642 33 06
France HIPRA FRANCE 7 rue Roland Garros, Batiment H 44700 - Orvault FRANCE Tél: +33 02 51 80 77 91	**Portugal** ARBUSET, Produtos Farmacêuticos e Sanitários De Uso Animal, Lda Portela de Mafra e Fontaínha - Abrunheira 2665 – 191 Malveira PORTUGAL Tel:+351 219 663 450
Hrvatska LABORATORIOS HIPRA, S.A. Avda. La Selva 135 17170 Amer (Girona) ŠPANJOLSKA Tel: +34 972 43 06 60	**România** LABORATORIOS HIPRA, S.A. Avda. La Selva 135 17170 Amer (Girona) SPANIA Tel: +34 972 43 06 60

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Ísland LABORATORIOS HIPRA, S.A. Avda. La Selva 135 17170 Amer (Girona) SPÁNN Sími: +34 972 43 06 60	**Slovenská republika** HIPRA SLOVENSKO, s.r.o. Zochova 5, 811 03 Bratislava, SLOVENSKO Tel: +421 02 32 335 223
Italia Hipra Italia S.r.l. Enrico Mattei, 2 25030 Coccaglio (BS) ITALIA Tel: +39 030 7241821	**Suomi/Finland** LABORATORIOS HIPRA, S.A. Avda. La Selva 135 17170 Amer (Girona) ESPANJA Puh/Tel: +34 972 43 06 60
Κύπρος LABORATORIOS HIPRA, S.A. Avda. La Selva 135 17170 Amer (Girona) ΙΣΠΑΝΙΑ Τηλ: +34 972 43 06 60	**Sverige** LABORATORIOS HIPRA, S.A. Avda. La Selva 135 17170 Amer (Girona) SPANIEN Tel. +34 972 43 06 60
Latvija LABORATORIOS HIPRA, S.A. Avda. La Selva 135 17170 Amer (Girona) SPĀNIJA Tel. +34 972 43 06 60	**United Kingdom (Northern Ireland)** LABORATORIOS HIPRA, S.A. Avda. La Selva 135 17170 Amer (Girona) SPAIN Tel. +34 972 43 06 60