

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:

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

3. PHARMACEUTICAL FORM

Suspension and solvent for suspension for injection.

4. 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)

5. TARGET SPECIES

Chicken embryonated eggs.

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

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

8. WITHDRAWAL PERIOD(S)

Withdrawal period: Zero days.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP

Once diluted use within 10 hours.

11. SPECIAL STORAGE CONDITIONS

Store and transport refrigerated.

Do not freeze.

Protect from light.

12. SPECIFIC 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. To be supplied only on veterinary prescription.

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

Laboratorios Hipra SA
Avda La Selva 135
17170 Amer (Girona)
Spain

16. MARKETING AUTHORISATION NUMBER

Vm 17533/5014

17. MANUFACTURER'S BATCH NUMBER

Batch

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. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Each dose (0.006 ml) of undiluted vaccine contains:

Eimeria acervulina, strain 044598 - 809
Eimeria maxima, strain 013352 - 476
Eimeria praecox, strain 007235 - 317
Eimeria tenella, strain 004221 - 299

3. CONTENTS 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)

4. ROUTE(S) OF ADMINISTRATION

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

5. WITHDRAWAL PERIOD(S)

Withdrawal period: zero days.

6. BATCH NUMBER

Batch

7. EXPIRY DATE

EXP
Once diluted use within 10 hours.

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

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 044598 - 809
Eimeria maxima, strain 013352 - 476
Eimeria praecox, strain 007235 - 317
Eimeria tenella, strain 004221 - 299

3. PHARMACEUTICAL FORM

Suspension and solvent for suspension for injection.

4. PACKAGE SIZE

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

5. TARGET SPECIES

Chicken embryonated eggs.

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

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

8. WITHDRAWAL PERIOD(S)

Withdrawal period: zero days.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP

Once diluted use within 10 hours.

11. SPECIAL STORAGE CONDITIONS

Store and transport refrigerated.

Do not freeze.

Protect from light.

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

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only. To be supplied only on veterinary prescription.

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

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Laboratorios Hipra SA
Avda La Selva 135
17170, Amer (Girona)
Spain

16. MARKETING AUTHORISATION NUMBER

Vm 17533/5014

17. MANUFACTURER'S BATCH NUMBER
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Batch

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard boxes (solvent bags)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

HIPRAHATCH solvent, for poultry vaccines

2. STATEMENT OF ACTIVE SUBSTANCES

3. PHARMACEUTICAL FORM

Solvent for suspension for injection.

4. PACKAGE SIZE

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

5. TARGET SPECIES

Chicken embryonated eggs.

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

In ovo administration.
Read the package leaflet supplied with the vaccine vial before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period: zero days.

9. SPECIAL WARNING(S), IF NECESSARY

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

10. EXPIRY DATE

EXP

11. SPECIAL STORAGE CONDITIONS

Do not store above 25 °C.

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

Disposal: read package leaflet supplied with the vaccine vial.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only. To be supplied only on veterinary prescription.

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

Laboratorios Hipra SA
Avda La Selva 135
17170 Amer (Girona)
Spain

16. MARKETING AUTHORISATION NUMBER

Vm 17533/5014

17. MANUFACTURER’S BATCH NUMBER

Batch

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Solvent bag

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

HIPRAHATCH solvent, for poultry vaccines

2. STATEMENT OF ACTIVE SUBSTANCES

3. PHARMACEUTICAL FORM

Solvent for suspension for injection.

4. PACKAGE SIZE

200 ml
400 ml
500 ml
800 ml
1,000 ml

5. TARGET SPECIES

Chicken embryonated eggs.

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

In ovo administration.

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

8. WITHDRAWAL PERIOD

Withdrawal period: zero days.

9. SPECIAL WARNING(S), IF NECESSARY

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

10. EXPIRY DATE

EXP

11. SPECIAL STORAGE CONDITIONS

Do not store above 25 °C.

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

Disposal: read package leaflet supplied with the vaccine vial.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only. To be supplied only on veterinary prescription.

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

Laboratorios Hipra SA
Avda La Selva 135
17170 Amer (Girona)
Spain

16. MARKETING AUTHORISATION NUMBER

Vm 17533/5014

17. MANUFACTURER’S BATCH NUMBER

Batch

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
EVANOVO suspension and solvent for suspension for injection 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 and manufacturer responsible for batch release:
Laboratorios Hipra SA
Avda La Selva 135
17170 Amer (Girona)
Spain

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

EVANOVO suspension and solvent for suspension for injection for chickens.

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

Active substances:

Each dose (0.006 ml) of undiluted vaccine contains:

<i>Eimeria acervulina</i> , strain 044	598 - 809*
<i>Eimeria maxima</i> , strain 013	352 - 476*
<i>Eimeria praecox</i> , strain 007	235 - 317*
<i>Eimeria tenella</i> , 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.

4. INDICATION(S)

For the active immunisation of chickens to reduce clinical signs, intestinal lesions and oocysts output associated with coccidiosis caused by *Eimeria acervulina*, *Eimeria maxima*, *Eimeria praecox* and *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. ADVERSE REACTIONS

None known.

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

Chicken embryonated eggs.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) 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, for poultry vaccines 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, for poultry vaccines 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, for poultry vaccines 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, for poultry vaccines 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, for poultry vaccines 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, for poultry vaccines 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
4 x 4,000 doses	2 x 8,000 doses	800 ml
4 x 2,500 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

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

10. WITHDRAWAL PERIOD(S)

Zero days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

EVANOVO suspension:

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

Do not freeze.

Protect from light.

HIPRAHATCH solvent, for poultry vaccines:

Do not store above 25 °C.

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.

12. SPECIAL WARNING(S)

Special warnings for each target species:

This product is intended for the vaccination of short-lived chickens only. No data are available on protection of longer-lived birds such as future layers/breeders. The vaccine will not protect species other than chickens against coccidiosis.

Special precautions for use in animals:

Vaccinate healthy embryos only.

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.

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 eggs vaccinated 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 (symptoms, emergency procedures, antidotes):

None.

Incompatibilities:

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

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Medicines should not be disposed of via wastewater or household waste. Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

November 2022

15. OTHER INFORMATION

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, for poultry vaccines.

Cardboard box with 10 bags containing 400 ml of HIPRAHATCH solvent, for poultry vaccines.

Cardboard box with 10 bags containing 500 ml of HIPRAHATCH solvent, for poultry vaccines.

Cardboard box with 10 bags containing 800 ml of HIPRAHATCH solvent, for poultry vaccines.

Cardboard box with 10 bags containing 1,000 ml of HIPRAHATCH solvent, for poultry vaccines.

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.

United Kingdom (Northern Ireland)

LABORATORIOS HIPRA, S.A.

Tel. +34 972 43 06 60

Approved 11 November 2022

A handwritten signature in black ink, appearing to read "Hunter." with a stylized, cursive flourish at the beginning.