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:

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Suspension and solvent for suspension for injection

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

4. CLINICAL PARTICULARS

4.1 Target species

Chicken embryonated eggs.

4.2 Indications for use, specifying the target species

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.

4.3 Contraindications

None.

4.4 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.

Vaccinate healthy embryos only.

4.5 Special precautions for use

Special precautions for use in animals

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.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

Not applicable.

4.8 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 of immunity has been demonstrated to be equivalent to those determined for EVANOVO and GUMBOHATCH when used alone. However, the duration of immunity following mixed use has not been investigated.
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.

4.9 Amounts to be administered and administration route

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.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

None.

4.11 Withdrawal period(s)

Zero days.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Immunological for Aves, live parasitic vaccines for domestic fowl.
ATC vet code: QI01AN01.

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

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

EVANOVO suspension:
Disodium phosphate dodecahydrate
Polysorbate 80
Potassium chloride
Potassium dihydrogen phosphate
Purified water
Sodium chloride

HIPRAHATCH solvent:
Disodium phosphate dodecahydrate
Potassium chloride
Potassium dihydrogen phosphate
Sodium chloride
Water for injections

6.2 Major incompatibilities

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

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 12 months.
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.

6.4. Special precautions for storage

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

HIPRAHATCH solvent:
Do not store above 25 ºC.

6.5 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:
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.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER

Vm 17533/5014

9. DATE OF FIRST AUTHORISATION

20 October 2022

10. DATE OF REVISION OF THE TEXT

June 2024

Gavin Hall
Approved: 06 June 2024