SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

GUMBOHATCH lyophilisate and solvent for suspension for injection for chickens

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose of reconstituted vaccine (0.05 ml for an in ovo dose or 0.2 ml for a subcutaneous dose) contains:

Active substance:
Live attenuated infectious bursal disease virus (IBDV), strain 1052 …….. $10^{1.18}$ – $10^{2.80}$ PU*
* PU: Potency Units

Excipients:
Unbound IBDV-specific egg antibodies……..17.07 – 21.32 NU** per vial
**NU: neutralising units

For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Lyophilisate: brown reddish colour.
Solvent: clear colourless solution.

4. CLINICAL PARTICULARS

4.1 Target species

Chickens and embryonated chicken eggs.

4.2 Indications for use, specifying the target species

For active immunisation of 1-day-old chicks and embryonated chicken eggs to reduce clinical signs and lesions of the bursa of Fabricius caused by very virulent avian infectious bursal disease virus infection.

The onset of immunity depends on the initial maternally derived antibodies (MDA) level of the batch of chickens and even then, will be different for individual chickens. In practice, studies in commercial chickens have shown an onset of immunity from between 24 days of age and 29 days of age.

Onset of immunity: Broiler chickens: from 24 days of age.
Future layer chickens: from 29 days of age.

Duration of immunity:

Broiler chickens: up to 45 days of age.
Future layer chickens: up to 71 days of age.

The efficacy of the vaccine has been demonstrated in chickens having an average MDA level from 4,500 to 5,100 ELISA units at hatching.

4.3 Contraindications

Do not use in flocks without MDAs against IBDV.

4.4 Special warnings for each target species

Vaccinate healthy animals only.

4.5 Special precautions for use

i). Special precautions for use in animals

This product should only be used after it has been demonstrated that very virulent IBDV strains are epidemiologically relevant in the area of vaccination.

Vaccinated birds may excrete the vaccine strain up to 3 weeks following vaccination. During this time, the contact of immunosuppressed and unvaccinated birds with vaccinated birds should be avoided.

Appropriate veterinary and husbandry measures should be taken to avoid spread of the vaccine strain to susceptible wild and domestic birds.

It is recommended to vaccinate all chickens on a site at the same time.

ii). Special precautions to be taken by the person administering the veterinary medicinal product to animals

Wash and disinfect hands and equipment after use.

Wash and disinfect hands after handling vaccinated birds or their litter because the virus is excreted by vaccinated birds for up to 3 weeks.

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.

iii). Other precautions

Not applicable.

4.6 Adverse reactions (frequency and seriousness)

Chickens and embryonated chicken eggs:

Very common (>1 animal / 10 animals treated):	Lymphocyte depletion followed by a lymphocyte repopulation and regeneration of the bursa of Fabricius. This depletion does not cause immunosuppression in chickens.

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 also the last section of the package leaflet for respective contact details.

4.7 Use during pregnancy, lactation or lay

The safety of the veterinary medicinal product has not been established during lay.

Do not use in birds in lay or breeding birds, or within 4 weeks before the start of the laying period.

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 EVANOVO prior to use and administered simultaneously in ovo. The product information of EVANOVO 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 IBD virus included in the GUMBOHATCH vaccine have been demonstrated to be equivalent to those determined for GUMBOHATCH 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.

4.9 Amount(s) to be administered and administration route

In ovo and subcutaneous use.

It is important to note that the volumes of solvent which must be used to reconstitute the vaccine are different depending on whether the vaccine will be administered in

ovo to embryonated eggs, or by subcutaneous injection to 1-day-old chicks. The final concentrations of the vaccines will therefore also differ.

Posology:

By the in ovo route: Administer one single injection of 0.05 ml of the reconstituted vaccine into each chicken egg at 18 days of embryonation.
By the subcutaneous route: Administer one single injection of 0.2 ml of the reconstituted vaccine to each chick at 1 day of age.

Method of administration:

For in ovo administration:

An automated egg injection machine can be used. The instructions for the calibration and use of the equipment should be strictly followed in order to deliver the appropriate dose.

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

Calculate and prepare the required volume of the vaccine as per the table below:

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

Number and content of vaccine vials:	HIPRAHATCH solvent volume to be used:
4 x 1,000 doses	200 ml
8 x 1,000 doses	400 ml
2 x 2,000 doses	200 ml
4 x 2,000 doses	400 ml
8 x 2,000 doses	800 ml
8 x 2,500 doses	1,000 ml
1 x 4,000 doses	200 ml
2 x 4,000 doses	400 ml
4 x 4,000 doses	800 ml
5 x 4,000 doses	1,000 ml
2 x 5,000 doses	500 ml
4 x 5,000 doses	1,000 ml
1 x 8,000 doses	400 ml
2 x 8,000 doses	800 ml
1 x 10,000 doses	500 ml
2 x 10,000 doses	1,000 ml

Reconstitution of the vaccine:

1. Withdraw 2 ml of the HIPRAHATCH solvent and inject into the vial containing the lyophilisate.

2. Mix the contents of the vial by gentle agitation until the contents are completely re-suspended, then withdraw the suspension obtained and inject it into the solvent bag.
3. Rinse the vial with another 2 ml of the HIPRAHATCH solvent/lyophilisate suspension obtained in step 1 and inject it back into the solvent bag.
4. Repeat step 2 to ensure that all the lyophilisate has been transferred into the solvent bag.
5. The reconstituted vaccine is a slightly reddish homogeneous suspension which should be used within 2 hours after reconstitution.

The vaccine (0.05 ml dose) must be injected into the amniotic sac of 18-day-old embryonated chicken eggs.

For subcutaneous administration:

An automated syringe can be used. The instructions for the calibration and use of the equipment should be strictly followed in order to deliver the appropriate dose.

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

Calculate and prepare the required volume of the vaccine as per the table below:

Dilutions for subcutaneous administration (0.2 ml per dose):

Number and content of vaccine vials:	HIPRAHATCH solvent volume to be used:
1 x 1,000 doses	200 ml
2 x 1,000 doses	400 ml
4 x 1,000 doses	800 ml
5 x 1,000 doses	1,000 ml
1 x 2,000 doses	400 ml
2 x 2,000 doses	800 ml
1 x 2,500 doses	500 ml
2 x 2,500 doses	1,000 ml
1 x 4,000 doses	800 ml
1 x 5,000 doses	1,000 ml

Reconstitution of the vaccine:

1. Withdraw 2 ml of the HIPRAHATCH solvent and inject into the vial containing the lyophilisate.
   Mix the contents of the vial by gentle agitation until the contents are completely resuspended, then withdraw the suspension obtained and inject it into the solvent bag.
2. Rinse the vial with another 2 ml of the HIPRAHATCH solvent/lyophilisate suspension obtained in step 1, and inject it back into the solvent bag.
3. Repeat step 2 to ensure that all the lyophilisate has been transferred into the solvent bag.

4. The reconstituted vaccine is a slightly reddish homogeneous suspension which should be used within 2 hours after reconstitution.

The vaccine (0.2 ml dose) must be injected under the skin of the neck of the 1-day-old chicks.

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

The following instructions should be used:

1. Taking into account the HIPRAHATCH solvent bag volume, prepare the EVANOVO vaccine.
2. Once the EVANOVO vaccine has been prepared, consider the bag volume to prepare enough GUMBOHATCH doses for the bag volume.
3. In each GUMBOHATCH vial to be used, insert 4 ml of the EVANOVO diluted vaccinal suspension prepared.
4. Once the lyophilized tablet is properly resuspended, introduce the volumes of the different GUMBOHATCH vials into the vaccinal bag.
5. Homogenize by moving the bag volume with the hands until having an even homogenate solution.
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

After the administration of a 10-fold overdose, a mild exudate and slight congestion in the bursa of Fabricius were very commonly observed.

4.11 Withdrawal period(s)

Zero days.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group:

To stimulate active immunity against very virulent bursal disease viruses (Gumboro disease) in chickens.

The vaccine contains an intermediate-plus IBDV strain bound to specific IBDV immunoglobulins, forming an immune-complex which is administered through vaccination.

ATCVet Code: QI01AD09

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lyophilisate:
Glycine
L-histidine
Sucrose
Disodium phosphate dodecahydrate
Potassium dihydrogen phosphate
Potassium chloride
Sodium chloride

HIPRAHATCH solvent, for poultry vaccines:
Disodium phosphate dodecahydrate
Potassium dihydrogen phosphate
Potassium chloride
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 this veterinary medicinal product or EVANOVO.

6.3 Shelf life

Shelf life of the lyophilisate as packaged for sale: 24 months.
Shelf life of the HIPRAHATCH solvent as packaged for sale: 3 years.
Shelf life after reconstitution according to directions: 2 hours.
Shelf life after mixing with EVANOVO: 2 hours.

6.4 Special precautions for storage

Lyophilisate:
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.

6.5 Nature and composition of immediate packaging

Lyophilisate:
Type I glass vials closed with Type I bromobutyl stoppers and sealed with aluminium caps containing 1,000 doses, 2,000 doses, 2,500 doses, 4,000 doses, 5,000 doses, 8,000 doses or 10,000 doses of the freeze-dried vaccine.

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

Package sizes:

In ovo and subcutaneous use:
Cardboard box with 10 lyophilisate vials containing 1,000 doses.
Cardboard box with 10 lyophilisate vials containing 2,000 doses.
Cardboard box with 10 lyophilisate vials containing 2,500 doses.
Cardboard box with 10 lyophilisate vials containing 4,000 doses.
Cardboard box with 10 lyophilisate vials containing 5,000 doses.

In ovo use only:
Cardboard box with 10 lyophilisate vials containing 8,000 doses.
Cardboard box with 10 lyophilisate vials containing 10,000 doses.
Cardboard box with 10 bags containing 200 ml HIPRAHATCH solvent.
Cardboard box with 10 bags containing 400 ml HIPRAHATCH solvent.
Cardboard box with 10 bags containing 500 ml HIPRAHATCH solvent.
Cardboard box with 10 bags containing 800 ml HIPRAHATCH solvent.
Cardboard box with 10 bags containing 1,000 ml 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 17533/5005

9. DATE OF FIRST AUTHORISATION

12 November 2019

10. DATE OF REVISION OF THE TEXT

May 2024

11. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Approved 18 May 2024