ANNEX I

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

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Unbound IBDV-specific egg antibodies	17.07 – 21.32 NU[1] per vial
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	

[1] NU: neutralising units

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

3. CLINICAL INFORMATION

3.1 Target species

Chickens and embryonated chicken eggs.

3.2 Indications for use for each 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.

3.3 Contraindications

Do not use in flocks without MDAs against IBDV.

3.4 Special warnings

Vaccinate healthy animals only.

3.5 Special precautions for use

Special precautions for safe use in the target species:

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 vaccine take. During this time, contact between the vaccinated chickens and any immunosuppressed or unvaccinated 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.

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 adverse reactions following 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.

3.6 Adverse events

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 its local representative 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

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.

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 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 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

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.
   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.
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 (0.05 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 according to the instructions in the EVANOVO product information.
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 in step 1.
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.

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

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

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: QI01AD09

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.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product, except the solvent supplied for use with this veterinary medicinal product and except those mentioned in section 3.8 above.

5.2 Shelf life

Shelf life of the lyophilisate as packaged for sale: 2 years.
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.

5.3 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.

5.4 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.

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/2/19/245/001-007

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 12/11/2019

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

{DD/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 (lyophilisate vials)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

GUMBOHATCH lyophilisate for suspension for injection for chickens

2. STATEMENT OF ACTIVE SUBSTANCES

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

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

3. PACKAGE SIZE

10 x 1 000 doses
10 x 2 000 doses
10 x 2 500 doses
10 x 4 000 doses
10 x 5 000 doses

4. TARGET SPECIES

Chickens and embryonated chicken eggs.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

In ovo or subcutaneous use.

To be mixed with HIPRAHATCH solvent.

7. WITHDRAWAL PERIODS

Withdrawal period: Zero days.

8. EXPIRY DATE

Exp. {mm/yyyy}
Once reconstituted use within 2 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/2/19/245/001 (10 x 1 000 doses)
EU/2/19/245/002 (10 x 2 000 doses)
EU/2/19/245/003 (10 x 2 500 doses)
EU/2/19/245/004 (10 x 4 000 doses)
EU/2/19/245/005 (10 x 5 000 doses)

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard boxes (lyophilisate vials)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

GUMBOHATCH lyophilisate for suspension for injection for chickens

2. STATEMENT OF ACTIVE SUBSTANCES

Each dose of reconstituted vaccine (0.05 ml for an *in ovo* dose) contains:

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

3. PACKAGE SIZE

10 x 8 000 doses
10 x 10 000 doses

4. TARGET SPECIES

Chickens and embryonated chicken eggs.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

In ovo use.

To be mixed with HIPRAHATCH solvent.

7. WITHDRAWAL PERIODS

Withdrawal period: Zero days.

8. EXPIRY DATE

Exp. {mm/yyyy}
Once reconstituted use within 2 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/2/19/245/006 (10 x 8 000 doses)
EU/2/19/245/007 (10 x 10 000 doses)

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Lyophilisate vial

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

GUMBOHATCH lyophilisate for suspension for injection for chickens

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Each dose (0.05 ml for *in ovo* or 0.2 ml for SC) contains:

Live attenuated IBDV, strain 1052 $10^{1.18} – 10^{2.80}$ PU*
* PU: Potency Units

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}
Once reconstituted use within 2 hours.

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

1 000 doses
2 000 doses
2 500 doses
4 000 doses
5 000 doses

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Lyophilisate vial

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

GUMBOHATCH lyophilisate for suspension for injection for chickens

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Each dose (0.05 ml for *in ovo*) contains:

Live attenuated IBDV, strain 1052 $10^{1.18} – 10^{2.80}$ PU*
* PU: Potency Units

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}
Once reconstituted use within 2 hours.

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

8 000 doses
10 000 doses

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 ºC.

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

GUMBOHATCH lyophilisate and solvent for suspension for injection for chickens

2. 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

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

3. Target species

Chickens and embryonated chicken eggs.

4. Indications for use

For active immunisation of 1-day-old chicks and embryonated chicken eggs to reduce clinical signs and lesions of 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.

5. Contraindications

Do not use in flocks without MDAs against IBDV.

6. Special warnings

Special warnings:
Vaccinate healthy animals only.

Special precautions for safe use in the target species:
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 vaccine take. During this time, contact between the vaccinated chickens and any immunosuppressed or unvaccinated 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.

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 adverse reactions following 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.

Laying birds:
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.

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 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:

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

Special restrictions for use and special conditions for use:
Not applicable.

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

7. Adverse events

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. 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 and subcutaneous use.

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.

9. Advice on correct administration

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.

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.
   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.
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 (0.05 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 according to the instructions in the EVANOVO product information.
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 in step 1.
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.

10. Withdrawal periods

Zero days.

11. Special storage precautions

Keep out of the sight and reach of children.

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.

Shelf life after reconstitution according to directions: 2 hours.
Shelf life after mixing with EVANOVO: 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 national collection systems applicable to the veterinary medicinal product concerned. 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/2/19/245/001-007

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.

15. Date on which the package leaflet was last revised

{DD/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:

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