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 AND OTHER 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. INDICATION(S)

6. ROUTES OF ADMINISTRATION

In ovo or subcutaneous use.

7. WITHDRAWAL PERIODS

Withdrawal period(s): Zero days.

8. EXPIRY DATE

EXP {month/year}
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 AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Laboratorios Hipra SA
Avda La Selva 135
17170 Amer (Girona)
Spain
Tel.: +34 972 43 06 60
Fax: +34 972 43 06 61
E-mail: hipra@hipra.com

14. MARKETING AUTHORISATION NUMBERS

Vm 17533/5005

15. BATCH NUMBER

Lot {number}

16. SPECIAL WARNING(S), IF NECESSARY

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

Disposal: read package leaflet.

18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

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 AND OTHER 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. INDICATION(S)

6. ROUTES OF ADMINISTRATION

In ovo use.

7. WITHDRAWAL PERIODS

Withdrawal period(s): Zero days.

8. EXPIRY DATE

EXP {month/year}
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 AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Laboratorios Hipra SA
Avda La Selva 135
17170 Amer (Girona)
Spain
Tel.: +34 972 43 06 60
Fax: +34 972 43 06 61
E-mail: hipra@hipra.com

14. MARKETING AUTHORISATION NUMBERS

Vm 17533/5005

15. BATCH NUMBER

Lot {number}

16. SPECIAL WARNING(S), IF NECESSARY

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

Disposal: read package leaflet.

18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

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 SUBSTANCE(S)

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 {month/year}
Once reconstituted use within 2 hours.

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

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

6. ROUTE(S) OF ADMINISTRATION

In ovo or SC use.

7. WITHDRAWAL PERIOD

Withdrawal period(s): Zero days.

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

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 SUBSTANCE(S)

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 {month/year}
Once reconstituted use within 2 hours.

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

8,000 doses
10,000 doses

6. ROUTE(S) OF ADMINISTRATION

In ovo use.

7. WITHDRAWAL PERIOD

Withdrawal period(s): Zero days.

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

PARTICULARS TO APPEAR ON THE OUTER PACKAGE - CARDBOARD BOXES (SOLVENT BAGS)

1. NAME OF THE DILUENT/SOLVENT

HIPRAHATCH solvent, for poultry vaccines

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

10 x 200 ml
10 x 400 ml
10 x 500 ml
10 x 800 ml
10 x1,000 ml

3. ROUTES OF ADMINISTRATION

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

4. STORAGE CONDITIONS

Do not store above 25 ºC.

5. BATCH NUMBER

Batch {number}

6. EXPIRY DATE

EXP {month/year}

7. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

LABORATORIOS HIPRA, SA

PARTICULARS TO APPEAR ON THE IMMEDIATE DILUENT/SOLVENT LABEL – SOLVENT BAG

1. NAME OF THE DILUENT/SOLVENT

HIPRAHATCH solvent, for poultry vaccines

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

10 x 200 ml
10 x 400 ml
10 x 500 ml
10 x 800 ml
10 x1,000 ml

3. ROUTES OF ADMINISTRATION

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

4. STORAGE CONDITIONS

Do not store above 25 ºC.

5. BATCH NUMBER

Batch {number}

6. EXPIRY DATE

EXP {month/year}

7. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

LABORATORIOS HIPRA, SA

PARTICULARS TO APPEAR ON THE 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 broiler chicks and embryonated broiler 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 broiler chickens have shown an onset of immunity from between 24 days of age and 28 days of age.

Onset of immunity: from 24 days of age.
Duration of immunity: up to 45 days of age.

The efficacy of the vaccine has been demonstrated in broilers 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 WARNING(S)

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 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.

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.

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 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.

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 or 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 using the contact details at the end of this leaflet, or via your national reporting system.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) 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.

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 broiler 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 broiler 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.

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.

10. WITHDRAWAL PERIOD(S)

Zero days.

11. SPECIAL STORAGE PRECAUTIONS

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.

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

12. SPECIAL PRECAUTIONS FOR DISPOSAL

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

13. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Marketing authorisation number: Vm 17533/5005

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

May 2023

16. CONTACT DETAILS

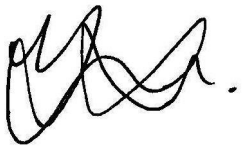
Marketing authorisation holder and manufacturer responsible for batch release and contact details to report suspected adverse reactions:

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

Local representative and contact details to report suspected adverse reactions:

United Kingdom (Northern Ireland)
LABORATORIOS HIPRA, SA
Tel. +34 972 43 06 60

17. OTHER INFORMATION



Approved: 24 April 2024