PACKAGE LEAFLET FOR:

HIPRAGUMBORO-G97 Lyophilisate for oral suspension.

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

HIPRAGUMBORO-G97

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

Composition per dose:
Live Infectious Bursal Disease Virus, strain GM97: 10^2 – 10^3 EID_{50} (embryo infective dose 50%).

Appearance: reddish tablet.

4. INDICATIONS

Chickens: For active immunisation of broilers with insignificant levels of maternally derived antibodies (ELISA of 500 or below) to reduce mortality, clinical signs and bursal lesions of Gumboro disease. Such birds can be vaccinated from one day of age. The onset of immunity is 14 days post vaccination and the duration 43 days post vaccination.

5. CONTRAINDICATIONS

Do not vaccinate sick birds.

Do not use in infected flocks showing clinical signs.

Do not use in layers and breeders.

6. ADVERSE REACTIONS

The administration of a single dose causes lymphocyte depletion in the bursa of Fabricius (in 50-75% of the follicles). Lymphocyte repopulation is observed from 14 days post vaccination onwards, at 28 days post vaccination there is still some depletion remaining (5-25 % of follicles). This lymphocyte depletion does not result in an immunosuppressive effect.

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Species: Chickens.
Category: Broilers.

8. DOSAGE FOR EACH SPECIES, ROUTE AND METHOD OF ADMINISTRATION

Dosage: 1 dose / bird.
Administration route: Oral.

Break the vacuum inside the vial by inoculation of 10 ml of drinking water without chlorine or disinfectants. Shake gently until complete resuspension of the freeze-dried powder before administration.

Posology:
Serologically negative birds can be vaccinated from one day of age. The optimum age for vaccination may be calculated using the level of maternal antibody in the chicks at day old (Kouwenhoven's formula) by testing at least 18 birds (preferably 24) of the flock according to the following table. All birds should be given a single vaccination only.

MEAN ELISA TITRE AT 1 DAY OF AGE	OPTIMUM AGE FOR VACCINATION (DAYS)
≤500	1
≤750	2-3
≤1000	4
≤1250	5-6
≤1500	7
≤2000	9
≤2500	11
≤3000	12-13
≤3500	14
≤4000	15-16
≤4500	17
≤5000	18
≤5500	19
≤6000	20

Method of administration:
The volume of water for reconstitution depends on the age of the birds and the management practice. Generally, 2 litres of water per 1,000 broilers for every day of age are needed. Hence, 1,000 14 day broilers would need 28 litres of water to reconstitute the 1,000 doses of vaccine. If the birds have higher or lower water requirements, adjust the volumes accordingly.
The way in which this vaccine is administered is critical. The following management considerations have been found to improve the vaccine intake:

Water should be withheld for 1-2 hours before vaccination to ensure that all reconstituted vaccine is consumed within 1-2 hours.
For bell drinkers: go round the house emptying and cleaning the drinkers during the water withholding period. Mix up the vaccine according to the recommendations and at the end of the water withholding period go round all the drinkers and fill them with water containing vaccine.
For nipple drinkers: a considerable amount of residual water may remain in the lines after the water withholding period. It is recommended to drain the lines and load them with water which contains vaccine before allowing the birds to have access to the nipples. Mix up the vaccine and apply to the tank. Calculate the volume that is left in the tank below the outlet valve and be sure to take this volume of water into account when calculating the number of doses to be added.
Always make sure that there is food available when vaccinating (birds will not drink if they have no food to eat). Turn on mains water when all the water containing vaccine has been consumed.

9. ADVICE ON CORRECT ADMINISTRATION

- Do not use water with chlorine or disinfectants to reconstitute the vaccine.

- Wash and disinfect hands and equipment after use.

10. WITHDRAWAL PERIOD

Zero days.

11. SPECIAL STORAGE PRECAUTIONS

- Keep out of the sight and reach of children.
- Store and transport refrigerated (2ºC -8 ºC).
- Protect from light.
- Do not use after the expiry date stated on the label /carton.
- Shelf life after diluition or reconstitution according to directions: 1 hour.

12. SPECIAL WARNINGS

- Use only in flocks with low levels of maternal antibodies (mean ELISA titres $\leq$ 500). The optimum day of vaccination of broilers with maternal antibodies is calculated according to the Kouwenhoven's formula.

- Due to its residual pathogenicity to the bursa the vaccine should be used only in areas contaminated with vvIBDV, except for infected flocks showing clinical signs.

- No information is available on the compatibility of this vaccine with any other. Therefore the safety and efficacy of this product when used with any other (either when used on the same day or different times) has not been demonstrated.

- Do not mix with any other vaccine or immunological product.

- The administration of a 10 fold dose causes lymphocyte depletion in the bursa of Fabricius (in approximately 75 % of follicles). Lymphocyte repopulation is observed from day 14 onwards and by day 28 post vaccination less than 25 % of follicles are affected.

- The vaccine strain spreads to unvaccinated chickens.

- Appropriate veterinary and husbandry measures should be taken to avoid spread to susceptible species.

- In the case of accidental ingestion, contact with the eyes, or spillage onto the skin seek medical advice immediately and show the package leaflet or the label to the physician.

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

Dispose of waste materials by boiling, incineration or immersion in an appropriate disinfectant approved for use by the competent authorities.

14. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

15. OTHER INFORMATION

Vm: 17433/5026

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

Presentation:

Pack with 1 vial of 1000 doses
Pack with 1 vial of 5000 doses
Pack with 10 vials of 1000 doses
Pack with 10 vials of 5000 doses

Not all pack sizes may be marketed.

PARTICULARS TO APPEAR ON THE OUTER PACKAGE (BOX)

10 vials of 1000 doses / 10 vials of 5000 doses

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

HIPRAGUMBORO-G97

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Composition per dose:

Live Infectious Bursal Disease Virus, strain GM97: 10^2 – 10^3 EID_{50} (embryo infective dose 50%).

3. PHARMACEUTICAL FORM

Lyophilisate for oral suspension.

4. PACKAGE SIZE

10 vials of 1000 doses
10 vials of 5000 doses

5. TARGET SPECIES

Chickens (Broilers).

6. INDICATIONS

Chickens: For active immunisation of broilers with insignificant levels of maternally derived antibodies (ELISA of 500 or below) to reduce mortality, clinical signs and bursal lesions of Gumboro disease. Such birds can be vaccinated from one day of age. The onset of immunity is 14 days post vaccination and the duration 43 days post vaccination.

7. METHOD AND ROUTE OF ADMINISTRATION

Dosage: 1 dose / bird.
Administration route: Oral, resuspended in the drinking water.

8. WITHDRAWAL PERIOD

Withdrawal period: Zero days.

9. SPECIAL WARNINGS, IF NECESSARY

Read the package leaflet before use

10. EXPIRY DATE

EXP {month/year}
Once reconstituted, administer the vaccine within a maximum of 1 hour.

11. SPECIAL STORAGE CONDITIONS

Store and transport refrigerated (2ºC -8 ºC).
Protect from light.

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

Dispose of waste materials by boiling, incineration or immersion in an appropriate disinfectant approved for use by the competent authorities.

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 17533/5026

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE (BOX)

1 vial of 1000 doses / 1 vial of 5000 doses

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

HIPRAGUMBORO-G97

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Composition per dose:

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Lyophilisate for oral suspension.

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1 vial of 1000 doses
1 vial of 5000 doses

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Chickens (Broilers).

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Read the package leaflet before use

7. METHOD AND ROUTE OF ADMINISTRATION

Dosage: 1 dose / bird.
Administration route: Oral, resuspended in the drinking water.

8. WITHDRAWAL PERIOD

Withdrawal period: Zero days.

9. SPECIAL WARNINGS, IF NECESSARY

Read the package leaflet before use

10. EXPIRY DATE

EXP {month/year}
Once reconstituted, administer the vaccine within a maximum of 1 hour.

11. SPECIAL STORAGE CONDITIONS

Store and transport refrigerated (2ºC -8 ºC).
Protect from light.

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

Dispose of waste materials by boiling, incineration or immersion in an appropriate disinfectant approved for use by the competent authorities.

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.

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LABORATORIOS HIPRA, SA.
Avda. La Selva, 135.
17170 - AMER (Girona) Spain.

16. MARKETING AUTHORISATION NUMBER

Vm 17533/5026

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS (LABEL)

1000 doses / 5000 doses

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

HIPRAGUMBORO-G97

2. QUANTITY OF THE ACTIVE SUBSTANCE

Composition per dose:

Live Infectious Bursal Disease Virus, strain GM97: 10^2 – 10^3 EID_{50} (embryo infective dose 50%).

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

1000 doses
5000 doses

4. ROUTE OF ADMINISTRATION

Oral, resuspended in the drinking water.

5. WITHDRAWAL PERIOD

Withdrawal period: Zero days.

6. BATCH NUMBER

Batch {number}

7. EXPIRY DATE

EXP {month/year}
Once reconstituted, administer the vaccine within a maximum of 1 hour.

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

Gavin Hall
Approved: 02 June 2026