ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

1 vial of 1 000 doses
1 vial of 5 000 doses
10 vials of 1 000 doses
10 vials of 5 000 doses

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

HIPRAGUMBORO-G97 lyophilisate for oral suspension

2. STATEMENT OF ACTIVE SUBSTANCES

Each dose contains:

Live infectious bursal disease virus, strain GM97: 10^2 – 10^3 EID_{50} (embryo infective dose 50%).

3. PACKAGE SIZE

1 vial of 1 000 doses
1 vial of 5 000 doses
10 vials of 1 000 doses
10 vials of 5 000 doses

4. TARGET SPECIES

Chickens (Broilers).

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral use.

7. WITHDRAWAL PERIODS

Withdrawal period: Zero days.

8. EXPIRY DATE

Exp. {mm/yyyy}

Once reconstituted use within a maximum of 1 hour.

9. SPECIAL STORAGE PRECAUTIONS

Store and transport refrigerated.
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, SA.

14. MARKETING AUTHORISATION NUMBERS

Vm 17533/3008

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Vial of 1 000 doses
Vial of 5 000 doses

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

HIPRAGUMBORO-G97

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Each dose contains:

Live infectious bursal disease virus, strain GM97: 10^2 – 10^3 EID_{50} (embryo infective dose 50%).

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}
Once reconstituted use within a maximum of 1 hour.

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

1 000 doses
5 000 doses

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

HIPRAGUMBORO-G97 lyophilisate for oral suspension for chickens

2. Composition

Each dose contains:

Active substance:
Live infectious bursal disease virus, strain GM97: 10^2 – 10^3 EID_{50} (embryo infective dose 50 %).

Reddish lyophilisate.

3. Target species

Chickens (Broilers).

4. Indications for use

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.

Onset of immunity: 14 days post vaccination.
Duration of immunity: 43 days post vaccination.

5. Contraindications

Do not use in infected flocks showing clinical signs.

6. Special warnings

Special warnings:
Use only in flocks with low levels of maternal antibodies (mean ELISA titres ≤ 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.

Vaccinate healthy animals only.

Special precautions for safe use in the target species:

The vaccine straincan spread to unvaccinated chickens. Special precautions should be taken to avoid spreading of the vaccine strain to unvaccinated chickens.

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

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Wash and disinfect hands and equipment after use.
In case of accidental ingestion, contact with the eyes, or spillage onto skin seek, medical advice immediately and show the package leaflet or the label to the physician.

Laying birds:
Do not use in birds in lay and breeding birds.
No studies to demonstrate the safety of this vaccine when it is administered to layers and breeders have been carried out.

Interaction with other medicinal products and other forms of interaction:
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:
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.

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

Major incompatibilities:
Do not mix with any other veterinary medicinal product.

7. Adverse events

Chickens (Broilers):

Very common (>1 animal / 10 animals treated):	Bursa of Fabricius lymphocyte depletion[1]

[1]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.

Reporting adverse events is important. It allows continuous safety monitoring of a 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:
E-mail: adverse.events@vmd.gov.uk
Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine

8. Dosage for each species, routes and method of administration

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

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
≤1 000	4
≤1 250	5-6
≤1 500	7
≤2 000	9
≤2 500	11
≤3 000	12-13
≤3 500	14
≤4 000	15-16
≤4 500	17
≤5 000	18
≤5 500	19
≤6 000	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

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.

10. Withdrawal periods

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 this veterinary medicinal product after the expiry date which is stated on thelabel /carton after Exp. The expiry date refers to the last day of that month.
Shelf life after reconstitution according to directions: 1 hour.

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 applicable national collection systems. 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 authorization number: Vm 17533/3008

Type I glass vials (European Pharmacopoeia) of 10 ml containing 1 000 doses and 5 000 doses of the freeze-dried vaccine, Type I bromobutyl rubber stoppers (European Pharmacopoeia) and aluminum caps.

Pack sizes**:**

Pack with 1 vial of 1 000 doses.
Pack with 1 vial of 5 000 doses.
Pack with 10 vials of 1 000 doses.
Pack with 10 vials of 5 000 doses.

Not all pack sizes may be marketed.

15. 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.

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

17. Additional information

Gavin Hall

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