ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

HIPRAGUMBORO CW lyophilisate for use in drinking water.

2. STATEMENT OF ACTIVE SUBSTANCES

Each dose contains:

Live attenuated infectious bursal disease virus, strain CH/80…….. $10^{3.5}$ – $10^{5.5}$ $CCID_{50}$ *
*cell culture infective dose 50 %.

3. PACKAGE SIZE

1 000 doses
5 000 doses
10 000 doses
10 x 1 000 doses
10 x 5 000 doses
10 x 10 000 doses

4. TARGET SPECIES

Chickens.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

In drinking water use.

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 (2 ºC - 8 ºC).
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

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15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Labels_lyophilisate vial

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

HIPRAGUMBORO CW lyophilisate for use in drinking water.

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Each dose contains:
Live attenuated infectious bursal disease virus, strain CH/80……$10^{3.5}$ – $10^{5.5}$ $CCID_{50}$*
* cell culture infective dose 50 %.

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

Once reconstituted use within 2 hours.

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

1 000 doses
5 000 doses
10 000 doses

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

HIPRAGUMBORO CW lyophilisate for use in drinking water.

2. Composition

Active substance:

Each dose contains:
Live attenuated infectious bursal disease virus, strain CH/80…….. $10^{3.5}$ – $10^{5.5}$ $CCID_{50}$ *
*cell culture infective dose 50 %.

Lyophilisate: Brown freeze-dried lyophilisate.

3. Target species

Chickens.

4. Indications for use

For active immunisation of chicken (broilers) with maternally derived antibodies (MDA ELISA breakthrough titre of 115) to prevent clinical signs and to reduce loss of weight and bursal damage caused by Gumboro Disease.
Onset of immunity: 14 days post vaccination.
Duration of immunity: 30 days post vaccination.

5. Contraindications

None.

6. Special warnings

Special warnings:

Vaccinate healthy animals only.
The optimal day of vaccination is calculated according to the Deventer's formula, applying an ELISA titre of 115 as the MDA breakthrough titre.

Special precautions for safe use in the target species:

Vaccinated chickens may excrete the vaccine strain up to 10 days following vaccination. During this time, the vaccine strain can spread to unvaccinated chicken.
Appropriate veterinary and husbandry measures should be taken to avoid spread of the vaccine strain to susceptible species.
The vaccine should not be used in birds without maternally derived antibodies (MDA).

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

Personal protective equipment consisting of impervious gloves should be worn when handling the veterinary medicinal product.
Wash and disinfect hands and equipment after use.
In 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.

Laying birds:

Do not use in birds in lay and breeding birds.

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:

No effects other than those indicated in section 7 have been observed following administration of ten doses.

Major incompatibilities:

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

7. Adverse events

Chickens.

Very rare (< 1 animal / 10 000 animals treated, including isolated reports):	Bursa Fabricius lymphocyte depletion[1]

[1] a notable and transient lymphocyte depletion can be observed in birds on day 7 post-vaccination. The repopulation of the follicles by lymphocytes starts after day 7 post-vaccination, being especially evident on 21 days post-vaccination. By day 28 post-vaccination only mild lesions remain in some birds. This does not result in an immune-supressive 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 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

Administer one dose of the vaccine per chicken in the drinking water.
Most of the commercial chicks are hatched with maternal derived antibodies, which might neutralise the vaccine. Therefore, it is required to calculate the proper vaccination time. The optimum age for vaccination is calculated by the Deventer Formula, after testing the level of maternally derived antibodies of 18-20 chicks of the flock.

According to this formula the optimum age of vaccination is as follows:

Optimum vaccination age =
{(Log_2 IBD antibody ELISA titre of bird(%) - Log_2 breakthrough titre of the vaccine) x $t_{0.5}$}
+ age at sampling + correction 0-4

IBD antibody ELISA titre of bird(%):

ELISA titre of the bird (at sampling) representing a certain percentage of the flock that is desired to be susceptible to the vaccine at the time of the application

Breakthrough titre of the vaccine:

ELISA titre that the vaccine is able to breakthrough

Half-life time of the antibodies (ELISA titre) in the type of chickens being sampled

Age at sampling:

Age of the birds at sampling

Correction 0-4:

Extra days when the sampling was done at 0 to 4 days of age.

Reconstitution and method of administration:
Only clean, cold, fresh, antiseptic and disinfectant free drinking water should be used for reconstitution of the vaccine.
Calculate the number of vials of vaccine required and the volume of water needed to vaccinate all the birds.
The needed volume of water for reconstitution of the vaccine depends on the daily water consumption which is related to the age of the birds, the environment temperature and the management practices. The volume of water should be adjusted to ensure that the vaccine solution is consumed in about 1 - 2 hours at the latest. If the birds have higher or lower water consumption times, adjust the volume accordingly to ensure the proper water consumption time.

Open the vaccine vial(s) and introduce 10 ml of water. Shake gently until the lyophilisate is completely dissolved. The reconstituted vaccine is a pinkish suspension. Transfer the suspension into a container containing the remaining volume for the final vaccine suspension. The empty vial(s) should be rinsed a couple of times to ensure the complete reconstitution of the vaccine.

Alternatively, fill a clean container with the appropriate amount of water, submerge each of the closed vaccine vials individually and open the vial(s) under water. Shake gently until the lyophilisate is completely dissolved. The empty vial should be rinsed a couple of times to ensure the complete reconstitution of the vaccine.

9. Advice on correct administration

The following management practices should improve the vaccine intake:

- Water should be withheld for 1-2 hours prior vaccination to increase the thirst of the birds and ensure that all reconstituted vaccine is consumed within 1 to 2 hours

Bell drinker vaccination: it is recommended to empty and clean the bell drinkers during the water withholding period. When the water restriction period is finished the vaccine is reconstituted as indicated previously and it is delivered to the birds.

Nipple drinker vaccination: a considerable amount of residual water might remain in the lines after the water withholding period. It is recommended to drain the lines and load them with the vaccine solution before allowing the birds to have access to the nipples.

Always ensure that the feed is available when vaccinating. The birds will not drink enough if they do not have access to feed.

10. Withdrawal periods

Zero days.

11. Special storage precautions

Keep out of the sight and reach of children.

Store and transport refrigerated (2 ºC - 8 ºC).
Do not freeze.
Protect from light.

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.

Shelf life after reconstitution according to directions: 2 hours

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.

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 numbers:

Pack size:
Cardboard box with 1 lyophilisate vial containing 1 000 doses
Cardboard box with 1 lyophilisate vial containing 5 000 doses

Cardboard box with 1 lyophilisate vial containing 10 000 doses
Cardboard box with 10 lyophilisate vials containing 1 000 doses
Cardboard box with 10 lyophilisate vials containing 5 000 doses
Cardboard box with 10 lyophilisate vials containing 10 000 doses

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

Local representatives and contact details to report suspected adverse reactions

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

17. Other information

Approved 21 November 2023