

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

HIPRAGUMBORO-G97 lyophilisate for oral suspension for chickens

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose contains:

### Active substance:

Live infectious bursal disease virus, strain GM97:10<sup>2</sup> - 10<sup>3</sup> EID<sub>50</sub> (embryo infective dose 50 %).

### Excipients:

Qualitative composition of excipients and other constituents
Disodium phosphate dodecahydrate
Potassium dihydrogen phosphate
Gelatin
Povidone 30
Sodium chloride
Potassium chloride
Monosodium glutamate
Sucrose
Water for injections

Reddish lyophilisate.

## 3. CLINICAL INFORMATION

### 3.1 Target species

Chickens (Broilers).

### 3.2 Indications for use for each target species

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.

### 3.3 Contraindications

Do not use in infected flocks showing clinical signs.

### 3.4 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 (see section 3.9.)

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.

### 3.5 Special precautions for use

Special precautions for safe use in the target species:

The vaccine strain can 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.

Special precautions for the protection of the environment:

Not applicable.

### 3.6 Adverse events

Chickens (Broilers):

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

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.

### 3.8 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.

### 3.9 Administration routes and dosage

**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
≤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.

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

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.

**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 infectious bursal disease (Gumboro disease) virus.

The vaccine strain GM97 induces a lesion score of 1.7 to the bursa of Fabricius observed 28 days after administration of 10 maximum doses.

**5. PHARMACEUTICAL PARTICULARS**

**5.1 Major incompatibilities**

Do not mix with any other veterinary medicinal product.

**5.2 Shelf life**

Shelf-life of the veterinary medicinal product as packaged for sale: 2 years.

Shelf life after reconstitution according to directions: 1 hour.

**5.3 Special precautions for storage**

Store and transport refrigerated (2 °C – 8 °C).

Protect from light.

**5.4 Nature and composition of immediate packaging**

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.

**5.5 Special precautions for the disposal of unused veterinary medicinal products 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, SA.

**7. MARKETING AUTHORISATION NUMBER(S)**

VPA10846/014/001

**8. DATE OF FIRST AUTHORISATION**

29/05/2015

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

18/11/2024

**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 \(https://medicines.health.europa.eu/veterinary\)](https://medicines.health.europa.eu/veterinary).