SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT.

HIPRAGUMBORO-G97

2. QUALITATIVE AND QUANTITATIVE COMPOSITION.

Composition per dose:

Active substance:

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

Excipients and adjuvants where knowledge of this is essential for the safe administration of the medicinal product:

None.

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM.

Lyophilisate for oral suspension.
Appearance: reddish tablet.

4. CLINICAL PARTICULARS.

4.1. Target species.

Species: Chickens.
Category: Broilers.

4.2. Indications for use, specifying the 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. The onset of immunity is 14 days post vaccination and the duration 43 days post vaccination.

4.3. Contraindications.

Do not vaccinate sick birds.

Do not use in infected flocks showing clinical signs.

Since no studies to demonstrate the safety of this vaccine when it is administered to layers and breeders have been carried out, its use is not recommended for these categories of the target species (see section 4.7).

4.4. Special warnings for each target species.

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 (see section 4.9. posology).

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.

See section 4.3.

4.5. Special precautions for use.

Special precautions for use in animals

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

- The vaccine strain spreads to unvaccinated chickens.

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

4.6. Adverse reactions (frequency and seriousness).

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.

4.7. Use during pregnancy, lactation or lay.

Do not use in layers and breeders (see section 4.3).

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

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.

4.9. Amounts to be administered and administration route.

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.

4.10. Overdose (symptoms, emergency procedures, antidotes), if necessary.

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.

4.11. Withdrawal period.

Zero days.

5. IMMUNOLOGICAL PROPERTIES.

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.

ATC vet code: QI01AD09

6. PHARMACEUTICAL PARTICULARS.

6.1. List of excipients

- Disodium phosphate dodecahydrate
- Potassium dihydrogen phosphate
- Gelatin
- Povidone 30
- Sodium chloride
- Potassium chloride
- Monosodium glutamate
- Sucrose
- Water for injections

6.2. Incompatibilities.

Do not mix with any other vaccine or immunological product.

6.3. Shelf-life.

Shelf-life of the veterinary medicinal product as packaged for sale: 24 months.

Shelf life after dilution or reconstitution according to directions: 1 hour.

6.4. Special precautions for storage.

Store and transport refrigerated (2ºC -8 ºC).

Protect from light.

6.5. 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 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.

6.6. Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products.

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

7. Name or corporate name and address or registered place of business of the Marketing Authorisation Holder.

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

8. Marketing Authorisation Number.

Vm17533/4002

9. Date of first authorisation.

Date: 26 July 2002

10. Date of revision of the text.

Date: March 2018

Conditions of supply / legal catagory.

To be supplied only on veterinary prescription.

Approved: 16/03/2018