

HIPRAGUMBORO GM97

Lyophilisate for oral suspension

QUALITATIVE AND QUANTITATIVE COMPOSITION OF THE ACTIVE SUBSTANCE:

Composition per dose:

Live Infectious Bursal Disease Virus, strain GM97: 10^2 - 10^3 EID₅₀
(embryo infective dose 50%).

INDICATIONS:

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.

CONTRAINDICATIONS:

Do not vaccinate sick birds.
Do not use in infected flocks showing clinical signs.

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.

TARGET SPECIES: Chickens (Broilers).

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

WITHDRAWAL PERIOD:

Zero days.

SPECIAL STORAGE PRECAUTIONS:

Keep out of the reach and sight of children.
Store and transport refrigerated (+2 °C - +8 °C). Protect from light.
Do not use after the expiry date stated on the label/carton.
Once reconstituted, administer the vaccine within a maximum of one hour.

SPECIAL WARNINGS:

Special warnings for each target species

Use only in flocks with low levels of maternal antibodies (ELISA titres less than 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 vIBDV, except for infected flocks showing clinical signs.

Special precautions for use in animals

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

Use during lay

Do not use in layers and breeders.

Interaction with other medicinal products when and other forms of interaction

No information is available on the safety and efficacy of this vaccine when used with any veterinary medicinal product, therefore to 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. This lymphocyte depletion does not result in an immunosuppressive effect.

Incompatibilities

Do not mix with any other vaccine or immunological product.

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

Any unused veterinary medicinal product or waste materials derived from such, veterinary medicinal product should be disposed of in accordance with local requirements.

OTHER INFORMATION:

Presentations:

Pack with 10 vials of 1,000 doses.
Pack with 10 vials of 2,500 doses.
Pack with 10 vials of 5,000 doses.
Not all pack sizes may be marketed.

Reg. n° 5/5/10/5307
Under veterinary prescription

FOR VETERINARY USE ONLY



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