SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

HIPRAGUMBORO
Lyophilisate for use in drinking water.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Composition per dose:

Active substance:
Live attenuated Infectious Bursal Disease Virus, strain CH/80…….. $10^{3.5}$ – $10^{5.5}$ $CCID_{50}$ (cell culture infective dose 50%).

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Lyophilisate for use in drinking water.
Appearance: brown freeze-dried tablet.

4. CLINICAL PARTICULARS

4.1 Target species

Chickens.

4.2 Indications for use,specifying the target species

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.
The onset of immunity is 14 days post vaccination.
The duration of immunity: 30 days post vaccination.

4.3 Contraindications

None.

4.4 Special warnings for each target species

The optimal day of vaccination is calculated according to the Deventer's formula, using 115 as the ELISA breakthrough titre value.

4.5 Special precautions for use

Special precautions for use in animals
Vaccinate healthy animals only.
The vaccine strain is excreted up to a maximum of 10 days; thus, during this time, it may spread to unvaccinated chickens.
Appropriate veterinary and husbandry measures should be taken to avoid cross contamination of flocks.
Do not use drinking water with chlorine or disinfectants.
The vaccine should not be used in birds without maternally derived antibodies.

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 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.

4.6 Adverse reactions (frequency and seriousness)

In very rare cases notable 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 specially 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.

The frequency of adverse reactions is defined using the following convention:
Very common (more than 1 in 10 animals displaying adverse reaction(s) during the course of one treatment).
-Common (more than 1 but less than 10 animals in 100 animals).
Uncommon (more than 1 but less than 10 animals in 1,000 animals).
Rare (more than 1 but less than 10 animals in 10,000 animals).
Very rare (less than 1 animal in 10,000 animals, including isolated reports).

4.7 Use during pregnancy, lactation or lay

Do not use in layers and breeders.

4.8 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.

4.9 Amounts to be administered and administration route

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

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

$t_{0.5}$:

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 of the vaccine:

Open the vaccine vial and introduce 10 ml of drinking water without chlorine or disinfectants. Shake gently until the complete reconstitution of the freeze-dried powder is achieved.
Other alternative is to open the vial under the water. The empty vial should be rinsed a couple of times to ensure the complete reconstitution of the vaccine.

Method of administration:

It is important to use clean cold water, free from chlorine and other disinfectants. The volume of water for reconstitution of the vaccine depends on the daily water consumption which is related with 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 1 hour up to 2 hours the maximum.
If the birds have higher or lower water consumption times, adjust the volume accordingly to ensure the proper water consumption time.

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.

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

No effects other than those indicated in section 4.6 have been observed following administration of ten doses.

4.11 Withdrawal period(s)

Zero days.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: immunologicals for Aves, live viral vaccines for domestic fowl.
ATCvet code: QI01AD09.

To stimulate active immunity against Infectious Bursal Disease (Gumboro disease) Virus.
The vaccine strain CH/80 is an intermediate strain with an average score of bursal lesion not higher than 2.0 (on a scale of 0-5) at 21 days post-vaccination and not higher than 1.2 at 28 days after administration of a 10 times maximum dose.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Disodium phosphate dodecahydrate

Potassium dihydrogen phosphate
Povidone
Potassium chloride
Sodium chloride
Sucrose
Monosodium glutamate
Water for injections

6.2 Incompatibilities

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

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 24 months
Shelf life after reconstitution according to directions: 2 hours.

6.4 Special precautions for storage

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

6.5 Nature and composition of immediate packaging

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

Pack size:
Pack with 1 vial of 1,000 doses
Pack with 1 vial of 5,000 doses
Pack with 1 vial of 10,000 doses
Pack with 10 vials of 1,000 doses
Pack with 10 vials of 5,000 doses
Pack with 10 vials of 10,000 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

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

7. MARKETING AUTHORISATION HOLDER

Laboratorios Hipra, S.A.
Avda. La Selva, 135
17170 Amer (Girona)
Spain

8. MARKETING AUTHORISATION NUMBER

Vm 17533/5017

9. DATE OF FIRST AUTHORISATION

02 August 2011

10. DATE OF REVISION OF THE TEXT

November 2023

Approved 21 November 2023