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 AND OTHER SUBSTANCES

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

3. PHARMACEUTICAL FORM

Lyophilisate for use in drinking water.

4. PACKAGE SIZE

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

5. TARGET SPECIES

Chickens.

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

The vaccine is administered in the drinking water.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Withdrawal period:Zero days.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Once reconstituted,use by 2 hours.

11. SPECIAL STORAGE CONDITIONS

Store and transport refrigerated.
Do not freeze.
Protect from light.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only.
To be supplied only on veterinary prescription.

14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reachof children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

16. MARKETING AUTHORISATION NUMBER

Vm 17533/5017

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

{LABEL}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Hipragumboro CW Lyophilisate for Use in Drinking Water

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

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

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

1,000 doses
5,000 doses
10,000 doses

4. ROUTE(S) OF ADMINISTRATION

The vaccine is administered in the drinking water.
Read the package leaflet before use.

5. WITHDRAWAL PERIOD

Withdrawal period: Zero days.

6. BATCH NUMBER

Batch {number}

7. EXPIRY DATE

EXP {month/year}
Once reconstituted, use by 2 hours.

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

PACKAGE LEAFLET FOR:

Hipragumboro CW Lyophilisate for Use in Drinking Water

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder and manufacturerresponsible for batch release:
LABORATORIOS HIPRA, S.A.
Avda. la Selva, 135
17170 Amer (Girona)
SPAIN

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Hipragumboro CW Lyophilisate for Use in Drinking Water

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Live attenuated Infectious Bursal Disease Virus, strain CH/80: $10^{3.5}$ – $10^{5.5}$ $CCID_{50}$ (cell culture infective dose 50%).
Appearance: brown freeze-dried tablet.

4. INDICATION(S)

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.

5. CONTRAINDICATIONS

None.

6. ADVERSE REACTIONS

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).

If you notice any serious effects or other effects not mentioned in this package leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Chickens

8. DOSAGE FOR EACH SPECIES, ROUTE(S) 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 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.

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 PERIOD

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 productafter 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 WARNING(S)

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.

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.

Use during pregnancy, lactation or lay:
Do not use in layers and breeders.

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 (symptoms, emergency procedures, antidotes):
No effects other than those indicated in section “Adverse reactions” have been observed following administration of ten doses.

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

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

Medicines should not be disposed of via wastewater or household waste.
Ask your veterinary surgeon how to dispose of medicines no longer required.
These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

November 2023

15. OTHER INFORMATION

The vaccine stimulates 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.

Pack sizes:
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.

Approved 21 November 2023