

LABELLING AND PACKAGE LEAFLET

A. LABELLING

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

LABEL
1000 doses

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Name of the product in United Kingdom: HIPRACOX BROILERS dw

Name of the product in Spain and Portugal: HIPRACOX ab.

Name of the product in France: HIPRACOX eb.

Name of the product in Sweden: HIPRACOX ad.

All other CMS: HIPRACOX dw.

Oral suspension for use in drinking water for chickens.

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

- Each 0.007 ml dose of vaccine contains the following numbers of sporulated oocysts derived from five precocious attenuated lines of coccidia:

Eimeria acervulina, strain 003.....300 – 390 *

Eimeria maxima, strain 013200 – 260 *

Eimeria mitis, strain 006.....300 – 390 *

Eimeria praecox, strain 007.....300 – 390 *

Eimeria tenella, strain 004.....250 – 325 *

* According to in vitro procedures of the manufacturer at the time of blending and at release.

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

1,000 doses (7 ml)

4. ROUTE(S) OF ADMINISTRATION

By oral route in the drinking water.

Read the package leaflet before use.

5. WITHDRAWAL PERIOD

Zero days.

6. BATCH NUMBER

Batch {number}

7. EXPIRY DATE

EXP {month/year}

Use the vaccine immediately after opening and discard unused vaccines.

Shelf life after dilution according to directions: it should not exceed 10 hours.

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

LABEL
5000 doses

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Name of the product in United Kingdom: HIPRACOX BROILERS dw
Name of the product in Spain and Portugal: HIPRACOX ab.
Name of the product in France: HIPRACOX eb.
Name of the product in Sweden: HIPRACOX ad.
All other CMS: HIPRACOX dw.

Oral suspension for use in drinking water for chickens.

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

- Each 0.007 ml dose of vaccine contains the following numbers of sporulated oocysts derived from five precocious attenuated lines of coccidia:

<i>Eimeria acervulina</i> , strain 003.....	300 – 390 *
<i>Eimeria maxima</i> , strain 013	200 – 260 *
<i>Eimeria mitis</i> , strain 006	300 – 390 *
<i>Eimeria praecox</i> , strain 007.....	300 – 390 *
<i>Eimeria tenella</i> , strain 004.....	250 – 325 *

* According to in vitro procedures of the manufacturer at the time of blending and at release.

3. PHARMACEUTICAL FORM

Oral suspension for use in drinking water.

4. PACKAGE SIZE

5,000 doses (35 ml)

5. TARGET SPECIES

Chicken (broiler).

6. INDICATION(S)

Live attenuated vaccine against Avian Coccidiosis.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

By oral route in the drinking water.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Zero days.

9. SPECIAL WARNING(S), IF NECESSARY

10. EXPIRY DATE

EXP {month/year}

Shelf life after first opening the immediate packaging: Use the vaccine immediately after opening and discard unused vaccines.

Shelf life after dilution according to directions: it should not exceed 10 hours.

11. SPECIAL STORAGE CONDITIONS

Store and transport refrigerated (+2 to + 8 °C). Protect from light. Do not freeze.

Keep in outer carton.

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

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

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 REACH AND SIGHT OF CHILDREN”

Keep out of the reach and sight of 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(S)

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARDBOARD BOX

1000 doses

5000 doses

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Name of the product in United Kingdom: HIPRACOX BROILERS dw

Name of the product in Spain and Portugal: HIPRACOX ab.

Name of the product in France: HIPRACOX eb.

Name of the product in Sweden: HIPRACOX ad.

All other CMS: HIPRACOX dw.

Oral suspension for use in drinking water in chickens.

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

- Each 0.007 ml dose of vaccine contains the following numbers of sporulated oocysts derived from five precocious attenuated lines of coccidia:

Eimeria acervulina, strain 003.....300 – 390 *

Eimeria maxima, strain 013200 – 260 *

Eimeria mitis, strain 006300 – 390 *

Eimeria praecox, strain 007.....300 – 390 *

Eimeria tenella, strain 004.....250 – 325 *

* According to in vitro procedures of the manufacturer at the time of blending and at release.

3. PHARMACEUTICAL FORM

Oral suspension for use in drinking water.

4. PACKAGE SIZE

1 bottle of 1,000 doses (7 ml).

1 bottle of 5,000 doses (35 ml).

Pack with 10 bottles of 1,000 doses (7 ml).

Pack with 10 bottles of 5,000 doses (35 ml).

Pack with 5 bottles of 5,000 doses (35 ml).

Pack with 6 bottles of 5,000 doses (35 ml).

5. TARGET SPECIES

Chicken (broiler).

6. INDICATION(S)

Live attenuated vaccine against Avian Coccidiosis.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

By oral route in the drinking water.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Zero days.

9. SPECIAL WARNING(S), IF NECESSARY

10. EXPIRY DATE

EXP {month/year}

Shelf life after first opening the immediate packaging: Use the vaccine immediately after opening and discard unused vaccines.

Shelf life after dilution according to directions: it should not exceed 10 hours.

11. SPECIAL STORAGE CONDITIONS

Store and transport refrigerated (+2 to + 8 °C). Protect from light. Do not freeze.

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

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

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 REACH AND SIGHT OF CHILDREN”

Keep out of the reach and sight of 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(S)

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

Name of the product in United Kingdom: HIPRACOX BROILERS dw

Name of the product in Spain and Portugal: HIPRACOX ab.

Name of the product in France: HIPRACOX eb.

Name of the product in Sweden: HIPRACOX ad.

All other CMS: HIPRACOX dw.

Oral suspension for use in drinking water for chickens.

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

LABORATORIOS HIPRA, S.A.

Avda. la Selva, 135

17170- AMER (Girona) SPAIN

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Name of the product in United Kingdom: HIPRACOX BROILERS dw

Name of the product in Spain and Portugal: HIPRACOX ab.

Name of the product in France: HIPRACOX eb.

Name of the product in Sweden: HIPRACOX ad.

All other CMS: HIPRACOX dw.

Oral suspension for use in drinking water for chickens.

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

Composition per dose (0.007 ml):

- Each 0.007 ml dose of vaccine contains the following numbers of sporulated oocysts derived from five precocious attenuated lines of coccidia:

Eimeria acervulina, strain 003.....300 – 390 *

Eimeria maxima, strain 013200 – 260 *

Eimeria mitis, strain 006.....300 – 390 *

Eimeria praecox, strain 007.....300 – 390 *

Eimeria tenella, strain 004.....250 – 325 *

* According to in vitro procedures of the manufacturer at the time of blending and at release.

Slightly brownish to white turbid oral suspension.

4. INDICATION(S)

For active immunisation of broiler chicks to reduce intestinal colonisation, intestinal lesions and clinical signs of Coccidiosis caused by *Eimeria acervulina*, *Eimeria maxima*, *Eimeria mitis*, *Eimeria praecox* and *Eimeria tenella*.

The onset of immunity is 14 days post-vaccination and the duration of protection is maintained at least for 28 days post-vaccination.

5. CONTRAINDICATIONS

None.

6. ADVERSE REACTIONS

After vaccination no general adverse effects have been observed.

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

The use of these type of vaccines may occasionally result in a temporary reduction in daily liveweight gain without any consequences on the final performances.

7. TARGET SPECIES

Chicken (broilers).

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Oral in the drinking water.

Chicken: 0.007 ml vaccine/bird, of 1 day of age.

Only hand-filled supplementary drinkers must be used.

Shake the suspension vigorously 5 to 10 times before use.

Dilute the vaccine in clean, room temperature water (avoid the use of very cold or very hot water) at a rate of 1,000 doses in up to ten litres.

Stir gently until the vaccine is fully homogenized.

Fill each drinker with 1 to 1.5 litres depending on the animals per drinker.

Administer a single dose of HIPRACOX BROILERS dw (0.007 ml) to each chick of 1 day of age.

9. ADVICE ON CORRECT ADMINISTRATION

Chickens must be strictly floor-reared on litter.

Litter should be removed and facilities and material cleaned between production cycles to reduce field infections.

Water should be withheld for 2-4 hours prior to vaccination.

Generally for drinking water administration, 10 litres of water per 1,000 one-day-old broiler chicks are needed. Ensure that you have mini drinkers at a rate of 1 drinker every 100-150 birds. Make sure that drinkers are clean and not placed under the brooders.

Provide adequate number of drinkers and distribute them homogeneously so that all chicks have access to the vaccinal water.

It is important to ensure that too many birds do not gather around one drinker.

Routine administration of water may continue when the treated water has been fully consumed.

10. WITHDRAWAL PERIOD

Zero days.

11. SPECIAL STORAGE PRECAUTIONS

Store and transport the vaccine refrigerated (+2 to +8 °C). Protect from light. Do not freeze.
Do not use after the expiry date stated on the label.
Shelf life after first opening the immediate packaging: Use the vaccine immediately after opening and discard unused vaccines.
Shelf life after dilution according to directions: it should not exceed 10 hours.
Keep out of the reach and sight of children.

12. SPECIAL WARNING(S)

Do not use in unhealthy or stressed birds.
Do not use in layers and breeders.
Do not mix with any other veterinary medicinal product.
No anticoccidial drugs or other agents having anti-coccidial activity via feed or water should be used for at least 3 weeks following vaccination of the chickens. The correct replication of the vaccine oocysts and consequently, the development of a solid immunity could be hindered. Additionally, the enhancement of protection produced by oocyst re-infections would also be limited.
Wash and disinfect hands and equipment after use.
Clean the affected area with soap and water in the case of accidental spillage onto the skin. In case of accidental ingestion, seek medical advice immediately and show the package insert or the label to the physician.
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 decided on a case by case basis.
The vaccine will not protect species other than chickens against Coccidiosis and is only effective against the *Eimeria* species indicated.

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

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

The vaccine stimulates active immunity against Coccidiosis caused by *Eimeria acervulina*, *Eimeria maxima*, *Eimeria mitis*, *Eimeria praecox* and *Eimeria tenella*.

Cardboard box with a 1,000 doses vial (7 ml).
Cardboard box with a 5,000 doses vial (35 ml).
Cardboard box with 10 vials of 1,000 doses (7 ml).
Cardboard box with 10 vials of 5,000 doses (35 ml).
Cardboard box with 5 vials of 5,000 doses (35 ml).
Cardboard box with 6 vials of 5,000 doses (35 ml).

Not all pack sizes may be marketed.
FOR ANIMAL TREATMENT ONLY
TO BE SUPPLIED ONLY ON VETERINARY PRESCRIPTION