

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS**

**LABEL**  
**1000 doses**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

HIPRACOX BROILERS Oral suspension 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:

<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. 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 or coarse spray.  
Read the package leaflet before use.

**5. WITHDRAWAL PERIOD**

Zero days.

**6. BATCH NUMBER**

Batch {number}

**7. 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.

Keep in outer carton.

**8. THE WORDS “FOR ANIMAL TREATMENT ONLY”**

For animal treatment only.

**NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER**

LABORATORIOS HIPRA, S.A.  
Avda. la Selva, 135  
17170- AMER (Girona) SPAIN

Local Representative  
HIPRA UK AND IRELAND, Ltd.  
Innovation Center, Office 503  
Bio City Nottingham Pennyfoot Street  
Nottingham  
NG1 1GF – UNITED KINGDOM  
e-mail: ukandireland@hipra.com

UK only: Vm 17533/4004. POM-V  
IE only: VPA. 10846/009/001. POM

**PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE**

**LABEL**  
**5000 doses**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

HIPRACOX BROILERS Oral suspension 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.

**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 or coarse spray.  
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 SIGHT AND REACH OF CHILDREN”**

Keep out of the sight and reach of children.

**15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER**

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**16. MARKETING AUTHORISATION NUMBER(S)**

UK only: Vm 17533/4004. POM-V  
IE only: VPA 10846/009/001. POM

**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**

HIPRACOX BROILERS Oral suspension 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.

**4. PACKAGE SIZE**

1 bottle of 1,000 doses.  
1 bottle of 5,000 doses.  
Pack with 10 bottles of 1,000 doses.  
Pack with 10 bottles of 5,000 doses.  
Pack with 5 bottles of 5,000 doses.  
Pack with 6 bottles of 5,000 doses.

**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 or coarse spray.  
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 SIGHT AND REACH OF CHILDREN”**

Keep out of the sight and reach of children.

**15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER**

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**16. MARKETING AUTHORISATION NUMBER(S)**

UK only: Vm 17533/4004. POM-V  
IE only: VPA 10846/009/001. POM

**17. MANUFACTURER'S BATCH NUMBER**

Batch {number}



**PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE**

**LABEL**

**1000 doses**

**5000 doses**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

UNIFLOCK

Sterile COLOURING AGENT for the administration of HIPRACOX BROILERS via coarse spray.

**2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES**

Composition per dose (0.02 ml):

Patent Blue V (E131)

Cochineal Red A Ponceau 4R (E124)

Vanillin flavour

**3. PHARMACEUTICAL FORM**

**4. PACKAGE SIZE**

1,000 doses (20 ml)

5,000 doses (100 ml)

**5. TARGET SPECIES**

**6. INDICATION(S)**

**7. METHOD AND ROUTE(S) OF ADMINISTRATION**

**8. WITHDRAWAL PERIOD**

**9. SPECIAL WARNING(S), IF NECESSARY**

Read the package leaflet enclosed with the vaccine

**10. EXPIRY DATE**

EXP {month/year}

**11. SPECIAL STORAGE CONDITIONS**

Store below 25°C. Do not freeze.  
Keep in outer carton.

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

Any unused product or waste materials should be disposed of in accordance with local requirements.

**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 reach of children.

**15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER**

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**16. MARKETING AUTHORISATION NUMBER(S)**

UK only: Vm 17533/4004. POM-V  
IE only: VPA 10846/009/001. POM

**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**

UNIFLOCK

Sterile COLOURING AGENT for the administration of HIPRACOX BROILERS via coarse spray.

**2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES**

Composition per dose (0.02 ml):

Patent Blue V (E131)

Cochineal Red A Ponceau 4R (E124)

Vanillin flavour

**3. PHARMACEUTICAL FORM**

**4. PACKAGE SIZE**

1 bottle of 1,000 doses.

1 bottle of 5,000 doses.

Pack with 10 bottles of 1,000 doses.

Pack with 10 bottles of 5,000 doses.

Pack with 5 bottles of 5,000 doses.

Pack with 6 bottles of 5,000 doses.

**5. TARGET SPECIES**

**6. INDICATION(S)**

**7. METHOD AND ROUTE(S) OF ADMINISTRATION**

**8. WITHDRAWAL PERIOD**

**9. SPECIAL WARNING(S), IF NECESSARY**

Read the package leaflet enclosed with the vaccine

**10. EXPIRY DATE**

EXP {month/year}

**11. SPECIAL STORAGE CONDITIONS**

Store below 25°C. Do not freeze.

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

Any unused product or waste materials should be disposed of in accordance with local requirements.

**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 reach of children.

**15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER**

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**16. MARKETING AUTHORISATION NUMBER(S)**

UK only: Vm 17533/4004. POM-V  
IE only: VPA 10846/009/001. POM

**17. MANUFACTURER’S BATCH NUMBER**

Batch {number}

**PACKAGE LEAFLET FOR:  
HIPRACOX BROILERS oral suspension for chickens.**

**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 manufacturer responsible for batch release:

LABORATORIOS HIPRA, S.A.  
Avda. la Selva, 135  
17170- AMER (Girona) SPAIN

**2. NAME OF THE VETERINARY MEDICINAL PRODUCT**

HIPRACOX BROILERS Oral suspension for chickens.

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

Composition per dose (0.007 ml) of HIPRACOX BROILERS:

**1. Active 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.

**2. Excipients and adjuvants:**

Diluent for coarse spray only: UNIFLOCK (0.02 ml/dose)

Slightly brownish to white turbid oral suspension.

**4. INDICATIONS**

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 42 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 package leaflet, please inform your veterinary surgeon.

## 7. TARGET SPECIES

Chicken (broilers).

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

Oral in the drinking water or coarse spray.

### Via 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 (0.007 ml) to each chick of 1 day of age.

### Via Coarse spray:

**Chicken:** 0.007 ml vaccine/bird + 0.02 ml UNIFLOCK/bird, of 1 day of age.

A suitable clean container of enough capacity (287 ml for 1000 doses or 1435 ml for 5000 doses) is required.

Add clean water at room temperature (260 ml for 1000 doses or 1300 ml for 5000 doses).

Shake the vial of UNIFLOCK. Add it into the water and stir gently until it is fully homogenized.

Shake the vial of HIPRACOX BROILERS. Add it into the mixture and stir gently until it is fully homogenized. Fill the spraying device with all the mixture and maintain it in continuous homogenisation.

Spray 28 ml of the mixture to 100 chicks. The pressure of the spraying device should be at 3 bars. The spraying device must provide a droplet size of  $\geq 100 \mu\text{m}$ .

## **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.

### Via Drinking water:

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

For the drinking water administration, the vaccine must only be administered with hand-filled supplementary drinkers. Do not use any other type of water distribution system for vaccination such as bell drinkers, nipple drinkers and automatic cup drinkers.

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.

### Via Coarse spray:

After vaccination, maintain the chicks inside the chick boxes for at least 1 hour. After this time, place the chicks in the litter and continue with regular management practices.

Use only the colouring agent UNIFLOCK.

## **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.

Store UNIFLOCK below 25°C. 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 sight and reach 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 except diluents or other component supplied for use with the product.

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. Seek medical advice immediately and show the package insert or the label to the physician if accidentally ingested.

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.

No anticoccidial drugs or other agents having anticoccidial 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.

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**

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

UNIFLOCK: Any unused product or waste materials should be disposed of in accordance with local requirements.

## **14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED**

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## 15. OTHER INFORMATION

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

### Pack sizes HIPRACOX BROILERS:

- Cardboard box with a 1,000 doses vial.
- Cardboard box with a 5,000 doses vial.
- Cardboard box with 10 vials of 1,000 doses.
- Cardboard box with 10 vials of 5,000 doses.
- Cardboard box with 5 vials of 5,000 doses.
- Cardboard box with 6 vials of 5,000 doses.

### Pack sizes UNIFLOCK:

- Cardboard box with a 1,000 doses vial.
- Cardboard box with a 5,000 doses vial.
- Cardboard box with 10 vials of 1,000 doses.
- Cardboard box with 10 vials of 5,000 doses.
- Cardboard box with 5 vials of 5,000 doses.
- Cardboard box with 6 vials of 5,000 doses.

Not all packs sizes of HIPRACOX BROILERS or UNIFLOCK may be marketed  
FOR ANIMAL TREATMENT ONLY  
TO BE SUPPLIED ONLY ON VETERINARY PRESCRIPTION  
UK only: Vm 17533/4004. POM-V: Prescription Only Medicine  
IE only: VPA 10846/009/001. POM: Prescription Only Medicine

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