

LABELLING AND PACKAGE LEAFLET

A. LABELLING HIPRACOX BROILERS spray

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 spray
All other CMS: HIPRACOX.

Suspension and solution for spray 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 coarse spray.
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 spray
All other CMS: HIPRACOX.

Suspension and solution for spray 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

Suspension and solution for spray.

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 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 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 spray
All other CMS: HIPRACOX.

Suspension and solution for spray 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

Suspension and solution for spray.

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 coarse spray.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Zero days.

9. SPECIAL WARNING(S), IF NECESSARY

The vaccine should always be supplied with UNIFLOCK (colouring agent)

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}

A. LABELLING UNIFLOCK

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

LABEL

1000 doses

5000 doses

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Name of the product in United Kingdom: UNIFLOCK. Sterile COLOURING AGENT for the administration of HIPRACOX BROILERS spray

Name of the product in Spain, Portugal, Poland: Colouring agent for use with Hipracox

Name of the product in Denmark: Colouring agent for spray

Name of the product other CMS: UNIFLOCK. Sterile COLOURING AGENT for the administration of HIPRACOX.

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Composition per dose (0.02 ml):

Patent Blue V (E131)

Cochineal Red A Ponceau 4R (E124)

Vanillin flavor

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.

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 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 IMMEDIATE PACKAGE

CARDBOARDBOX

1000 doses

5000 doses

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Name of the product in United Kingdom: UNIFLOCK. Sterile COLOURING AGENT for the administration of HIPRACOX BROILERS spray

Name of the product in Spain, Portugal, Poland: Colouring agent for use with Hipracox

Name of the product in Denmark: Colouring agent for spray

Name of the product other CMS: UNIFLOCK. Sterile COLOURING AGENT for the administration of HIPRACOX.

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Composition per dose (0.02 ml):

Patent Blue V (E131)

Cochineal Red A Ponceau 4R (E124)

Vanillin flavor

3. PHARMACEUTICAL FORM

4. PACKAGE SIZE

1 bottle of 1,000 doses (20 ml).

1 bottle of 5,000 doses (100 ml).

Pack with 10 bottles of 1,000 doses (20 ml).

Pack with 10 bottles of 5,000 doses (100 ml).

Pack with 5 bottles of 5,000 doses (100 ml).

Pack with 6 bottles of 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.

UNIFLOCK should always be supplied with HIPRACOX BROILERS spray.

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 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 spray
All other CMS: HIPRACOX.

Suspension and solution for spray 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 spray
All other CMS: HIPRACOX.

Suspension and solution for spray for chickens.

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

Composition per dose (0.007 ml) of HIPRACOX BROILERS spray:

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.

UNIFLOCK (0.02 ml/dose)

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 by coarse spray.

Chicken: 0.007 ml vaccine/bird + 0.02 ml UNIFLOCK (colouring agent)/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 (colouring agent). Add it into the water and stir gently until it is fully homogenized.

Shake the vial of HIPRACOX BROILERS spray. 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.

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 UNIFLOCK (colouring agent).

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 (colouring agent) 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 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 except diluents or other component supplied for use with the 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.

The vaccine will not protect species other than chickens against Coccidiosis and is only effective against the *Eimeria* species indicated.

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.

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

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

UNIFLOCK (colouring agent): 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

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 spray:

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 (colouring agent):

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