

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Hipracox Broilers Oral suspension for chicken

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

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 (0.02ml /dose)

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Slightly brownish to white turbid oral suspension.

4 CLINICAL PARTICULARS

4.1 Target Species

Chicken (broilers).

4.2 Indications for use, specifying the target species

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.

4.3 Contraindications

None.

4.4 Special warnings for each target species

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

4.5 Special precautions for use

Special precautions for use in animals

Chickens must be strictly floor-reared on litter.

Do not vaccinate unhealthy or stressed birds.

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.

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

See section 6.2. (Incompatibilities).

For coarse spray administration, use only the colouring agent UNIFLOCK.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

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.

4.6 Adverse reactions (frequency and seriousness)

None.

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 interactions

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.

4.9 Amounts to be administered and administration route

Administer one dose of vaccine (which corresponds to 0.007 ml of the 1,000 and 5,000 doses presentations) to each 1-day old chick. All birds should be given a single dose.

The method of administration is by oral route in the drinking water or coarse spray.

Method of administration (drinking water):

For the administration of the vaccine, hand-filled supplementary drinkers must be used (see section 4.5.).

Water should be withheld for 2-4 hours prior to vaccination (this time includes the transportation from the hatchery to the farm).

Provide adequate number of mini-drinkers or drinking space so that all chicks have access to the vaccinal water and thus, can receive the correct dose of the vaccine.

Distribute homogeneously the mini-drinkers in the area where chicks are housed at a rate of 1 mini-drinker for every 100-150 birds. Preferably distribute the drinkers in a line under or next to the area where the definitive drinkers will be placed.

Make sure that mini-drinkers are thoroughly cleaned and not placed under the brooders.

Once the mini-drinkers are placed, shake the vial of vaccine vigorously 5 to 10 times before opening.

Thoroughly mix the content of the vial with the appropriate amount of clean and room temperature water 10 litres or 50 litres of water for 1,000 doses and 5,000 doses, respectively). Avoid the use of very cold or very hot water.

Stir gently until the vaccine is fully homogenized in the water.

Fill each mini-drinker with 1 to 1.5 litres depending on the rate of animals per drinker (1 litre for 100 birds per drinker or 1.5 litres for 150 birds per mini-drinker).

It is important to ensure that too many birds do not gather around one mini-drinker. If so, walk through the birds softly to increase the chance of weaker birds to obtain access to the mini-drinkers and thus, to the vaccinal water.

Remove the mini-drinkers once the water has been fully consumed and routine administration of water may continue.

Method of administration (coarse spray):

Before starting the preparation, a suitable clean container of enough capacity is required to prepare the Vaccine Solution (VS) (a minimum volume of 287 ml or 1435 ml of capacity for each 1000 or 5000-dose vial, respectively).

To prepare the VS, the Colouring Agent Solution (CAS) should be prepared first.

To prepare the CAS shake the vial of Colouring Agent (UNIFLOCK) vigorously. Dilute the contents of the vial with clean room temperature water (260 ml or 1300 ml of water for each 1000 or 5000-dose vial, respectively).

Once the CAS is prepared, shake the vial of HIPRACOX BROILERS vigorously and dilute the contents into the CAS to prepare the VS (280 ml or 1,400 ml of CAS for each 1000 or 5000-dose vial, respectively).

Fill the vaccine reservoir of the spraying device with all the VS prepared.

Maintain the VS in continuous homogenisation. The vaccine is administered via coarse spray to the chicks, by spraying 28 ml of the VS for each 100 chicks. The pressure of the spraying device should be at 3 bars. The spraying device must provide a droplet size of ≥ 100 micrometres.

In order to improve the uniformity of the vaccination maintain the chicks inside the chick box for at least 1 hour in order to let them ingest all the vaccine droplets.

After this time, place the chicks in the litter and continue with regular management practices.

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

None.

4.11 Withdrawal period(s)

Zero days.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Live parasitic vaccines, coccidia

ATCvet code: QI01AN01

To stimulate active immunity against Coccidiosis caused by *Eimeria acervulina*, *Eimeria maxima*, *Eimeria mitis*, *Eimeria praecox* and *Eimeria tenella*.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Hipracox broilers Uniflock

Phosphate Buffered Solution (PBS): Patent Blue V (E131)

- Potassium Chloride Cochineal Red A Ponceau 4R (E124)

- Disodium Phosphate 12 H₂O Vanillin

- Potassium Dihydrogen Phosphate Phosphate Buffered Solution (PBS):
- Sodium Chloride - Potassium Chloride
- Disodium Phosphate 12H₂O
- Potassium Dihydrogen Phosphate
- Sodium Chloride

6.2 Major incompatibilities

Do not mix with any other veterinary medicinal product except diluents or other components supplied for use with the product.

6.3 Shelf-life

HIPRACOX BROILERS:

Shelf-life of the veterinary medicinal product as packaged for sale: 6 months.

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

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

UNIFLOCK:

Shelf-life of the veterinary medicinal product as packaged for sale: 12 months.

6.4 Special precautions for storage

HIPRACOX BROILERS:

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

UNIFLOCK:

Store below 25°C. Do not freeze.

6.5 Nature and composition of immediate packaging

The containers of HIPRACOX BROILERS are made of 10-ml and 50-ml Type I (1,000 and 5,000 doses) colourless glass flasks with Type I polymeric elastomer closures and aluminium Flip-caps.

The containers of UNIFLOCK are made of 20-ml and 100-ml Type II (1,000 and 5,000 doses) colourless glass flasks with Type I polymeric elastomer closures and aluminium caps.

Sales presentation:

HIPRACOX BROILERS and UNIFLOCK are packed independently. Both are packed with the same sales presentation:

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 pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

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 national requirements.

7 MARKETING AUTHORISATION HOLDER

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

8 MARKETING AUTHORISATION NUMBER(S)

VPA10846/009/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 31 October 2007

Date of last renewal: 02 September 2011

10 DATE OF REVISION OF THE TEXT