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. QUALITATIVE AND QUANTITATIVE COMPOSITION

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:

Eimeria acervulina, strain 003.....300 – 390 *
Eimeria maxima, strain 013.....200 – 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.

2. Excipients and adjuvants.

UNIFLOCK (0.02 ml/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 28 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.
Litter should be removed and facilities and material cleaned between production cycles to reduce field infections.
See section 6.2. (Incompatibilities).
Use only the colouring agent UNIFLOCK (colouring agent).

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. In case of accidental ingestion, seek medical advice immediately and show the package insert or the label to the physician.

4.6 Adverse reactions (frequency and seriousness)

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.

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 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 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 coarse spray.

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 UNIFLOCK (colouring agent) 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 spray 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 μm.

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. 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 spray
Phosphate Buffered Solution (PBS):
- Potassium Chloride
- Disodium Phosphate $12H_2O$
- Potassium Dihydrogen Phosphate
- Sodium Chloride

UNIFLOCK (colouring agent)
Patent Blue V (E 131)
Cochineal Red A Ponceau 4R (E 124)
Vanillin
Phosphate Buffered Solution (PBS):
- Potassium Chloride
- Disodium Phosphate $12H_2O$
- Potassium Dihydrogen Phosphate
- Sodium Chloride

6.2 Incompatibilities

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

6.3 Shelf life

HIPRACOX BROILERS spray:
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 vaccines.
Shelf-life after dilution according to directions: 10 hours.

UNIFLOCK (colouring agent):
Shelf-life of the veterinary medicinal product as packaged for sale:: 1 year.

6.4. Special precautions for storage

HIPRACOX BROILERS spray:
Store and transport refrigerated (+2 – +8 ºC). Protect from light. Do not freeze.

UNIFLOCK (colouring agent):
Store below 25ºC. Do not freeze.

6.5 Nature and composition of immediate packaging

The containers of HIPRACOX BROILERS spray 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 (colouring agent) are made of 20-ml and 100-ml Type II (1,000 and 5,000 doses) colourled glass flasks with Type I polymeric elastomer closures and aluminium caps.

Sales presentation:

HIPRACOX BROILERS spray and UNIFLOCK (colouring agent) 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 product or waste materials derived from the use of such products

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.

7. MARKETING AUTHORISATION HOLDER

LABORATORIOS HIPRA, SA.
Avda. la Selva, 135.
17170 - AMER (Girona) Spain.

8. MARKETING AUTHORISATION NUMBER(S):

Vm 17533/4008.

9. DATE OF FIRST AUTHORISATION

23 May 2007

10. DATE OF REVISION OF THE TEXT

August 2012

PROHIBITION OF SALE, SUPPLY AND/OR USE.

Non-applicable