SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Name of the product in United Kingdom: HIPRACOX BROILERS dw
Name of the product in Spain: HIPRACOX agua de bebida.
Name of the product in 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. QUALITATIVE AND QUANTITATIVE COMPOSITION

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 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.

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.
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).

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 oral route in the drinking water.

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.

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

Potassium Chloride
Disodium Phosphate 12 H2O
Potassium Dihydrogen Phosphate
Sodium Chloride

6.2 Incompatibilities

Do not mix with any other veterinary medicinal product.

6.3 Shelf life

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 or reconstitution according to directions: 10 hours.

6.4. Special precautions for storage

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

6.5 Nature and composition of immediate packaging

The containers 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.

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

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

7. MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER

Vm 17533/4007

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