

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Paracox-5, suspension for oral suspension for chickens

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substances:

Each 0.004 ml dose of vaccine contains the following numbers of sporulated oocysts derived from five precocious attenuated lines of coccidia:

<i>Eimeria acervulina</i> HP	500 – 650 oocysts*
<i>Eimeria maxima</i> CP	200 – 260 oocysts*
<i>Eimeria maxima</i> MFP	100 – 130 oocysts*
<i>Eimeria mitis</i> HP	1000 – 1300 oocysts*
<i>Eimeria tenella</i> HP	500 – 650 oocysts*

*According to the in vitro counting procedure of the manufacturer at the time of blending and at release.

Solvent for spray-on-chickens

Carminic acid (Red colourant, E120)

Xanthan gum (E415)

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Suspension for oral suspension.

Vaccine: aqueous suspension

Solvent for spray-on-chickens: semi-opaque, red, viscous solution.

4 CLINICAL PARTICULARS

4.1 Target Species

Chickens.

4.2 Indications for use, specifying the target species

Spray-on-feed, spray-on-chicken without solvent or in drinking water

For the active immunisation of chickens to reduce infection and clinical signs of coccidiosis caused by *Eimeria acervulina*, *E. maxima*, *E. mitis* and *E. tenella*.

Onset of immunity: begins to develop within 14 days post vaccination.

Duration of immunity: at least 40 days post vaccination.

Spray-on-chickens with solvent

For the active immunisation of chickens against coccidiosis caused by *Eimeria acervulina*, *E. maxima*, *E. mitis* and *E. tenella*:

- to reduce oocyst excretion for *E. acervulina*, *E. maxima*, and *E. tenella*.
- to reduce loss in weight gain for *E. acervulina*, *E. mitis* and *E. tenella*.

Onset of immunity: 21 days post vaccination.

Duration of immunity: 10 weeks.

4.3 Contraindications

None.

4.4 Special warnings for each target species

Vaccinate healthy animals only. Do not administer to stressed chicks, e.g. chilled, not feeding or drinking.

For administration by spray on chickens, a red food colouring agent (Cochineal E120) should be added to the diluted vaccine, or the vaccine should be diluted using the recommended 'Solvent for spray-on-chickens'.

For the spray-on-chicken method of administration a significant reduction in efficacy may be observed if diluted in tap water without red colourant. The purity of the cochineal E120 must be in compliance with Commission Directive 95/45/EC.

Chickens should be strictly floor reared on litter. 'Paracox-5' vaccine contains live coccidia and is dependent upon replication of the vaccinal lines within the host for development of protection.

It is common to find oocysts in the gastrointestinal tract of vaccinated birds from 1-3 weeks or more after vaccination. These oocysts are most likely to be vaccinal oocysts which recycle in the birds via the litter. Recycling ensures satisfactory flock protection against all the pathogenic species of *Eimeria* contained in the vaccine.

Measures should be taken to ensure that the bulk diluted vaccine is resuspended at intervals during administration.

Since the protection against coccidial infection following Paracox-5 administration is enhanced by natural challenge, it should be noted that access to any therapeutic agents having anti-coccidial activity at any time following vaccination may reduce the duration of effective protection. This is important throughout the life of the chicken.

To reduce the chance of coccidial field challenge before the onset of immunity, litter should be removed and chicken housing should be thoroughly cleaned between rearing cycles.

4.5 Special precautions for use

Special precautions for use in animals

Ensure that all vaccination equipment is thoroughly cleaned before use.

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

Personal protective equipment consisting of well-fitting masks and eye protection should be worn when spraying the vaccine.

4.6 Adverse reactions (frequency and seriousness)

Mild lesions of e.g. *E. acervulina*, and *E. tenella* (lesion scores of +1 or +2 using the numerical ranking system of Johnson and Reid, 1970) have commonly been discovered in birds 3 to 4 weeks after vaccination in laboratory studies. Lesions of this severity will not affect the performance of immune chickens.

The frequency of adverse reactions is defined using the following convention:

- Very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- Common (more than 1 but less than 10 animals in 100 animals treated)
- Uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- Rare (more than 1 but less than 10 animals in 10,000 animals treated)
- Very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

4.7 Use during pregnancy, lactation or lay

Laying birds

Do not use in birds in lay.

4.8 Interaction with other medicinal products and other forms of interactions

Do not administer anticoccidial agents including sulphonamides and antibacterial agents before or after vaccination with Paracox-5.

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 made on a case by case basis.

4.9 Amounts to be administered and administration route

A single dose of Paracox-5 should be administered to chickens from one day of age by spray-on-feed, by spray-on-chickens, or at 3 days old via drinking water.

Administration via feed

Sufficient starter feed for the first 24-48h should be laid out on paper or plastic along the floor of the poultry house. Do not administer the vaccine via an automatic feeding machine or place treated feed directly under heating lamps.

Shake the container vigorously for 30 seconds before use, to ensure re-suspension of the oocysts. Dilute Paracox-5 in water at the rate of approximately 5000 doses in up to 3 litres of water and spray evenly over the surface of the feed using a coarse spray. Ensure a controlled, even coverage of the total surface area of the feed available to the chicks. Agitate the applicator reservoir regularly throughout application to avoid settling out of oocysts. Ensure that all available feed is treated and that the total number of doses dispensed matches the number of birds in the house.

Once the vaccine has been diluted for use it should be sprayed onto feed and birds should be placed with access to the feed within two hours.

When the treated allocation of feed has been consumed, routine feeding may continue.

Administration via drinking water

Place chicks in the house at day-old and encourage them to become accustomed to the nipple drinker system. When the chicks are 3 days old the lighting system is turned off for about 7 hours. Raise all drinking lines out of reach of the chicks for about two hours before administration of the vaccine. At the same time the lighting is switched on. Drain each drinking line completely.

Dilute the vaccine to a concentration of 1 dose/2 - 4ml in cold tap water. Calculate the average number of birds per drinking line and calculate the volume of diluted vaccine needed per drinking line at a rate 2 - 4 ml per bird.

Fill each line with diluted vaccine and lower to allow the birds access to the nipples. An initial charge (about 1 litre) of an indicator (e.g. milk) can be used to show when the line has been filled to the end and can be closed, without wasting vaccine. As the birds drink, keep each line full via its reservoir until all the diluted vaccine prepared for that line has been added. Normal water supply then follows.

It is recommended that before using the vaccine in a facility for the first time, precautions are taken to check that the procedure ensures the drinking lines have been properly primed with Paracox-5, as shown by the appearance of the indicator from nipples at the end the line, before the chicks are allowed to start drinking.

Administration via spray-on-chickens

For administration by spray-on-chickens, red food colouring agent (Cochineal E120) should be added to the diluted vaccine, or the vaccine should be diluted using the

recommended solvent 'Solvent for spray-on chickens'. The solvent contains red colouring agent and xanthan gum, both of which are included for better uptake.

a) Solvent for spray-on-chickens

Vaccine should be delivered using a dose volume of between 0.21 and 0.28 ml diluted vaccine per bird using a coarse spray. Determine the delivery capacity of the spray device in terms of the volume delivered per 100 birds. Multiply this volume by 50 to give the total volume of diluted vaccine required for 5,000 doses (or by 10 for 1,000 doses). I.e. for the preparation of 5000 doses diluted vaccine, a total of $0.21 \times 5000 = 1050$ ml diluted vaccine is needed and is divided over the vaccine, solvent and water as below:

1. 20 ml Paracox-5 vaccine (1 vial)
2. 500 ml Solvent (1 bottle)
3. Fill up to 1050 ml with tap water

Water used for vaccine dilution should be fresh, cool and free of pollution. Take a clean container for vaccine preparation, add the solvent to the container and add the calculated amount of water to the container, and mix solvent and water to a uniform solution. Shake the 5000 dose (or 1000 dose) vial of Paracox-5 vigorously for 30 seconds to ensure re-suspension of the oocysts. Add the entire contents of the vial into the container with solvent and water and mix thoroughly.

Add the diluted vaccine to the applicator reservoir and spray evenly over the birds using a coarse spray. Ensure a controlled, even coverage of the total internal surface area of the box containing the chickens. Leave the birds in the box for at least 30 minutes in a well-lighted area to allow time for the birds to preen.

b) Red food colouring agent (E120).

Vaccine should be delivered using a dose volume of between 0.21 and 0.28 ml diluted vaccine per bird using a coarse spray. Determine the delivery capacity of the spray device in terms of the volume delivered per 100 birds. Multiply this volume by 50 to give the total volume of diluted vaccine required for 5,000 doses (or by 10 for 1,000 doses) and add this volume of water to a suitable container (normally between 1.0 and 1.5 litres for 5,000 doses or 200 and 300 ml for 1,000 doses). Uptake of the vaccine by the birds, and therefore the efficacy of the vaccine, is improved if a red food colouring agent is added to the diluted vaccine before administration by spray. Add sufficient red food colouring agent (cochineal E120) to the water to give a concentration of 0.1% w/v, equivalent to 210-280 µg/bird.

Shake one 5,000 dose (or 1,000 dose) vial of Paracox-5 vigorously for 30 seconds to ensure resuspension of the oocysts. Add the entire contents of the vial to the diluent and mix thoroughly. Add the diluted vaccine to the applicator reservoir and operate the cabinet to spray evenly over the birds using a coarse spray.

Ensure a controlled, even coverage of the total internal surface area of the box

containing the chicks. Agitate the applicator reservoir regularly throughout application to avoid settling out of oocysts. Leave the birds in the box for at least 30 minutes in a well-lighted area to allow time for the birds to preen.

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

Severe overdose (x5 or more) may lead to a temporary reduction in daily live-weight gain.

4.11 Withdrawal period(s)

Zero days.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: immunologicals for aves, domestic fowl, live parasitic vaccines, coccidia.

ATC Vet Code: QI01AN01.

Induces specific immunity to wild strains of these *Eimeria* species when ingested by chickens.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Paracox-5

Phosphate buffered saline

Solvent for spray-on-chickens

Sodium chloride

Carminic acid (red colourant, (E120)

Xanthan gum (E415)

Water for injection

6.2 Major incompatibilities

Do not mix with any other veterinary medicinal product except the solvent recommended for use for spray administration.

6.3 Shelf-life

Paracox-5

Shelf life of the veterinary medicinal product as packaged for sale: 33 weeks.

Shelf life after dilution according to directions: use immediately.

Solvent for spray-on-chickens

Shelf life as packaged for sale: 24 months.

6.4 Special precautions for storage

Paracox-5

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

Solvent for spray-on-chickens

Store between 2°C - 25°C

6.5 Nature and composition of immediate packaging

Paracox-5

The containers are 4 ml and 20 ml plastic vials made of clear, colourless PETG (polyethylene terephthalate copolyester) with bromobutyl stoppers and aluminium crimps. The crimp is a 20 mm Flip-Tear-Up made of clear lacquered aluminium with a white polypropylene disc. Vials are packaged in boxes.

5 x 4ml (1000 doses)

5 x 20ml (5000 doses)

Solvent for spray-on-chickens

The solvent containers are plastic PET bottles closed with a rubber stopper and sealed with an aluminium cap.

For administration by spray-on-chickens, Solvent for spray-on-chickens can be used to dilute the vaccine. The appropriate volume of solvent is supplied together with the vaccine (100 ml solvent for 1000 doses, 500 ml for 5000 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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Intervet Ireland Limited
Magna Drive
Magna Business Park, Citywest Road
Dublin 24

Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA10996/215/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 28th June 1999

Date of last renewal: 17th February 2010

10 DATE OF REVISION OF THE TEXT

May 2018