SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Paracox-5 suspension for oral suspension for chickens

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 0.004 ml dose of vaccine contains:

Active substances:

Sporulated oocysts derived from five precocious lines of coccidia:

Eimeria acervulina, strain HP, live	500 – 650 oocysts*
Eimeria maxima, strain CP, live	200 – 260 oocysts*
Eimeria maxima, strain MFP, live	100 – 130 oocysts*
Eimeria mitis, strain HP, live	1000 – 1300 oocysts*
Eimeria tenella, strain HP, live	500 – 650 oocysts*

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

Excipients:

Qualitative composition of excipients and other constituents
Suspension:
Phosphate buffered saline
Solvent for spray-on-chickens:
Carminic acid (Red colourant, E120)
Xanthan gum (E415)
Sodium chloride
Water for injections

Suspension: milky suspension after mixing.
Solvent for spray-on-chickens [Solvent for Paracox for spray-on-chickens administration (BE)]:
semi-opaque, red, viscous solution.

3. CLINICAL INFORMATION

3.1 Target species

Chickens.

3.2 Indications for use for each 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: 14 days after vaccination.
Duration of immunity: 40 days after 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 after vaccination.
Duration of immunity: 10 weeks after vaccination.

3.3 Contraindications

None.

3.4 Special warnings

Vaccinate healthy animals only.

3.5 Special precautions for use

Special precautions for safe use in the target species:
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. The 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 the vaccine 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.
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.

Special precautions for the protection of the environment:
Not applicable.

Other precautions:
Not applicable

3.6 Adverse events

Chickens:

Common (1 to 10 animals / 100 animals treated):	Intestinal lesion.[1].

[1] Mild intestinal 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. Lesions of this severity will not affect the performance of immune chickens.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Laying birds:
Do not use in birds in lay.

3.8 Interaction with other medicinal products and other forms of interaction

Do not administer anticoccidial agents including sulphonamides and antibacterial agents before or after vaccination with the veterinary medicinal product.
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.

3.9 Administration routes and dosage

A single dose of the vaccine 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 - 48 hours 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 the vaccine 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 - 4 ml 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 the vaccine, 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 5000 doses (or by 10 for 1000 doses). I.e. for the preparation of 5000 doses diluted vaccine, a total of 0.21 × 5000 = 1050 ml diluted vaccine is needed and is divided over the vaccine, solvent and water as below:

1. 20 ml 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 the vaccine 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 5000 doses (or by 10 for 1000 doses) and add this volume of water to a suitable container (normally between 1.0 and 1.5 litres for 5000 doses or 200 and 300 ml for 1000 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 5000 dose (or 1000 dose) vial of the vaccine vigorously for 30 seconds to ensure resuspension of the oocysts. Add the entire contents of the vial to the solvent 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.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

Severe overdose (5 fold or more) may lead to a temporary reduction in daily live-weight gain.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Zero days.

4. IMMUNOLOGICAL INFORMATION

4.1 ATCvet code: QI01AN01.

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

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

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

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 33 weeks.
Shelf life of solvent as packaged for sale: 2 years.
Shelf life after dilution according to directions: use immediately.

5.3 Special precautions for storage

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

Solvent
Store between 2 °C – 25 °C.

5.4 Nature and composition of immediate packaging

Vaccine
Clear, colourless PETG (polyethylene terephthalate copolyester) vial, closed with bromobutyl stopper and sealed with an aluminium cap.

Pack sizes:
Box with 5 vials containing 4 ml (1000 doses)
Box with 5 vials containing 20 ml (5000 doses)

Solvent
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.

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

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

FOR UK(NI) ONLY:
Medicines should not be disposed of via wastewater.
Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirement.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Intervet International B.V.

7. MARKETING AUTHORISATION NUMBER

Vm 06376/3033

8. DATE OF FIRST AUTHORISATION

28 June 1999

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

February 2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

UK: Find more product information by searching for the 'Product Information Database' or 'PID' on www.gov.uk.>

Gavin Hall

Approved: 25 February 2025