Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Paracox suspension for oral suspension for chickens

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substances:
Vaccine:
Each 0.1 ml of vaccine contains the following numbers of live sporulated oocysts* derived from eight precocious lines of coccidia:

E. acervulina HP	500 per dose
E. brunetti HP	100 per dose
E. maxima CP	200 per dose
E. maxima MFP	100 per dose
E. mitis HP	1000 per dose
E. necatrix HP	500 per dose
E. praecox HP	100 per dose
E. tenella HP	500 per dose

*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)

Excipients
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 or in drinking water
For the active immunisation of healthy chickens to reduce infection and clinical signs of coccidiosis caused by *Eimeria acervulina, E.brunetti, E. maxima, E. mitis, E. necatrix*, *E. praecox*, and *E. tenella*.

Onset of immunity: begins to develop within 10 days post vaccination.
Duration of immunity: at least 36 weeks when birds are housed in conditions that permit oocyst recycling.

Spray-on-chickens
For the active immunisation of chickens against coccidiosis caused by *Eimeria acervulina, E. brunetti, E. maxima, E. mitis, E. necatrix, E. praecox,* and *E. tenella*:
- to reduce oocyst excretion for *E. acervulina, E. brunetti, E. maxima, E. necatrix, E. praecox and E. tenella.*
- to reduce loss in weight gain for *E. acervulina, E. brunetti, E. mitis, E. necatrix, E. praecox 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.

4.5 Special precautions for use

Special precautions for use in animals

Food and water provided at any stage before or after vaccination must be free from anticoccidial agents including sulphonamides and antibacterial agents having anticoccidial activity.

The vaccine contains live coccidian oocysts 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/litter. This ensures satisfactory flock protection against all the pathogenic strains of the same species of *Eimeria* that are contained in the vaccine.

Chickens should be healthy and floor-reared on deep litter.
Litter should be removed and chicken housing thoroughly cleaned and disinfected between rearing cycles. This will reduce the chances of a coccidial field challenge occurring before the development of adequate flock protection.
Particular care should be taken to ensure that all chicks take water when vaccinated by pipeline nipples at day-old.
Ensure that all vaccination equipment is thoroughly cleaned before use.
Do not administer to dry drinkers.

In any animal population there may be a small number of individuals which fail to respond fully to vaccination. Successful vaccination depends upon correct administration of the vaccine together with the animal's ability to respond. This can be influenced by such factors as genetic constitution, intercurrent infection, age, the presence of maternally derived antibodies, nutritional status, concurrent drug therapy and stress.

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

For administration by spray-on-chickens the vaccine should be diluted using 'Solvent for spray-on-chickens'.

Wash hands immediately after use.
Personal protection equipment consisting of masks and eye protection should be worn when spraying the vaccine.

4.6 Adverse reactions (frequency and seriousness)

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

Since the protection against coccidial infection following vaccine administration is enhanced by natural challenge, it should be noted that access to any therapeutic agents having anticoccidial activity at any time following vaccination may reduce the duration of effective protection. This is particularly important in the four weeks following vaccination.

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

For oral administration to chickens by spray-on-feed, by spray-on-chickens, or in drinking water. A single dose of vaccine (0.1 ml undiluted vaccine) should be administered to chickens between day-old and 9 days of age, inclusive.

It is necessary to shake and massage the sachet vigorously for 30 seconds before use to ensure homogeneous suspension of the oocysts.
The vaccine contains xanthan gum which will aid the suspension of oocysts in the water providing it is used within the recommendations made below.

a) in drinking water

Pipeline drinkers with nipples

The product may be administered in water via line drinkers from first placement of the chicks at 1 day of age, provided that a procedure is used that ensures consumption of the vaccinated water evenly by all chicks, avoiding settlement of oocysts. For example, the following methods have been shown to be successful:

The vaccine should be diluted to a concentration of 1 dose per 2 ml in cold tap water and well stirred immediately before use. Calculate the total volume of water in the drinker system to be used, the average number of birds per drinking line and therefore the number of drinker lines and volume of diluted vaccine required. For static drinker lines, it is recommended that birds should be thirsted for 1-2 hours prior to administration. Each line should be drained and primed under gravity with diluted vaccine immediately before allowing 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. Turn on the mains water supply when all of the diluted vaccine has been consumed. For drinker lines temporarily connected up to a re-circulating system, it is recommended that vaccine dilution be carried out in a temporary reservoir incorporated within the

circulation system, ensuring that the contents remain well mixed at all times. In order to mix the oocysts evenly, the diluted vaccine should be allowed to re-circulate for at least 2.5 hours through the drinker lines before the birds are allowed to drink.

The above examples are intended as a guide to illustrate the principles that should be followed in adapting a particular pipeline drinker system.
Due to the difficulties associated with getting very young birds to drink from nipple drinkers, particular care should be taken to ensure that chicks of 1-3 days old take sufficient water for vaccine uptake when vaccinated using this method.

Alternatively, vaccination using supplementary drinkers between 5-9 days may be preferred. Occasionally on farms using nipple lines, supplementary drinkers are provided for the first 4-5 days. These may be fount-type drinkers or small bell-type drinkers which are automatically fed from the nipple line. If each supplementary drinker of this type is fed individually from the line, then the method of vaccination is essentially similar to bell-type drinkers. If, however, these drinkers are fed in sequence from a single nipple, one may encounter problems of air-locks after this type of drinker has been disconnected in order to deprive the birds of water for the 1-2 hours before vaccination. In this case it may be more appropriate to make an initial dilution of vaccine in a suitable container, *e.g*. a watering can, and pour the diluted vaccine into each drinker, as for individual founts.

Automatic Circular Drinkers (Bell-type)
'Paracox' may be administered into individual drinkers. It is strongly advised that a single type of drinker is used and that the birds are fully accustomed to these drinkers before vaccination. This method therefore is not suited to day-old chickens. The appropriate amount of vaccine for delivery into each drinker is calculated thus:

$$\frac{\text{Total number of chickens per house (or pen)}}{\text{Total number of drinkers per house (or pen)}} \times 0.1 = \text{Amount of vaccine per drinker}$$

The vaccine is delivered into each drinker through a short 19 gauge cannula attached to an automatic syringe. A suitable cannula is included with each 100 or 500 ml pack. The syringe is directed at an oblique angle to the surface of the water and moved around the drinker during delivery to ensure an even distribution of the vaccine. Care should be taken to ensure that the vaccination syringe is accurately calibrated.

Raise drinkers up to 2 hours before vaccination. Ensure that the drinkers are clean and adjust each valve if appropriate to make certain that drinkers contain a suitable volume of water (250 - 400 ml).
Deliver the appropriate volume of vaccine into each drinker as described above. Lower drinkers immediately. The minimum volume of vaccine which should be

delivered is 10 ml per drinker and the maximum is 25 ml, i.e., ensure that there are between 100 and 250 birds per drinker. Water supply to the drinkers should not be turned off during vaccination, i.e., allow drinkers to refill automatically as the birds drink.

Line Drinkers with gravity-fed cups
Where nipple lines are equipped with gravity-activated cups at each position, vaccine is delivered directly into each cup. The method is generally similar to that for bell-type drinkers. Vaccine volume is likely to be between 3 and 5 ml per drinker.

Trough Drinkers
Method is essentially similar to that for Bell-type drinkers. Drain or remove drinkers up to 2 hours before vaccination. Ensure drinkers are clean. Allow them to refill immediately before delivery of an appropriate volume of vaccine. As a guide to the number of drinkers required at vaccination, there should be approximately 0.25-1.00 cm drinker space per bird.

Fount-type drinkers (manually filled)
Remove drinkers up to 2 hours before vaccination. Ensure drinkers are clean. Ensure that drinkers are filled with water and replaced immediately before delivery of an appropriate volume of vaccine. As a guide to the number of drinkers required at vaccination, there should be approximately 0.25-1.00 cm drinker space per bird.

IMPORTANT
The vaccine should be diluted no more than 1/50. The vaccine should not be administered into the main header tank of the watering system. The dilution of vaccine would be too high and the oocysts would not remain in suspension.

b) on feed

A method of application should be chosen that ensures rapid, even coverage of the total surface area of the feed available to the chicks. The vaccine may be sprayed, using a coarse spray, either neat or diluted in water. If the vaccine is diluted, not more than four volumes of water should be added to one volume of vaccine (5000 doses of Paracox added to 2 litres of water). Care should be taken to ensure that the applicator reservoir is agitated regularly throughout application to avoid settling out of oocysts.

c) Spray-on-chickens

Vaccine should be delivered using a dose volume of 0.21 ml of 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 × 5000 = 1050

ml diluted vaccine is needed and is divided over the vaccine, solvent and water as below:

1. 500 ml Paracox vaccine (1 sachet)
2. 500 ml Solvent (1 bottle)
3. Fill up to 1050 ml with tap water

The solvent contains red colouring agent and xanthan gum, both of which are included for better uptake. 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 and massage the 5000 dose (or 1000 dose) sachet of Paracox vigorously for 30 seconds to ensure re-suspension of the oocysts. Add the entire contents of the sachet 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.

Information about the sachet

The all-plastic sachet is self-collapsing and does not require a vent needle. The contents will remain sterile and cannot be tampered with until opened by inserting the plastic probe (affixed to the delivery tube). The sachet may be suspended from the operator's belt or neck.

Instructions on use of the sachet

Attach open end of delivery tube (included in each pack) to a suitably calibrated, automatic syringe. Centre the plastic probe (affixed to the delivery tube) onto the circular stud at the base of the sachet. Using sharp, firm pressure, force the probe straight through the stud membrane. The probe will snap-lock into a secure operating position within the stud. A small amount of extra vaccine is added to each sachet to allow for priming of the syringe.

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

Severe overdose (x 5 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.
ATCvet code: QI01AN01.

Paracox is an attenuated, live coccidiosis vaccine for oral administration to chickens. Induces specific immunity to wild strains of *Eimeria* species contained in this vaccine, when ingested by chickens.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Paracox
Xanthan gum (E415)
Purified water

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
Shelf-life of the veterinary medicinal product as packaged for sale: 28 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
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
100 ml and 500 ml flexible nylon/polyethylene sachets. Each sachet has a holding strap and header card attached. Sachets are packed individually in a cardboard box. A sterile clear PVC delivery tube with a white opaque polypropylene angle probe and a blunt ended cannular is provided.

Solvent for spray-on-chickens
The solvent containers are plastic PET vials closed with a rubber stopper and sealed with an aluminium cap.
For administration by spray-on-chickens, the vaccine is supplied together with the appropriate volume of solvent (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
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Magna Business Park, Citywest Road
Dublin 24
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA10996/245/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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Date of last renewal: 17th February 2010

10 DATE OF REVISION OF THE TEXT

December 2018