## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Paracox-8 suspension for oral suspension for chickens

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 0.004 ml dose of vaccine contains:

**Active substances:**
Live sporulated oocysts derived from eight precocious lines of coccidia:

| | |
|---|---|
| *E. acervulina*, strain HP, live | 500 oocysts* |
| *E. brunetti*, strain HP, live | 100 oocysts * |
| *E. maxima*, strain CP, live | 200 oocysts * |
| *E. maxima*, strain MFP, live | 100 oocysts * |
| *E. mitis*, strain HP, live | 1000 oocysts * |
| *E. necatrix*, strain HP, live | 500 oocysts * |
| *E. praecox*, strain HP, live | 100 oocysts * |
| *E. tenella*, strain HP, live | 500 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***: |
| Sodium chloride |
| Disodium phosphate (hydrate) |
| Potassium di-hydrogen phosphate |
| Potassium chloride |
| Purified water |
| ***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 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: 10 days.
Duration of immunity: 36 weeks.

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.
Duration of immunity: 10 weeks.

## 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:

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 reared on floor with litter. Litter should be removed, and chicken housing thoroughly cleaned and disinfected between rearing cycles, to minimize carry over to the next flock. 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.

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 veterinary medicinal product.

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

### 3.6 Adverse events

Chickens:

| | |
|---|---|
| Common<br>(1 to 10 animals / 100 animals treated): | Intestinal lesion[1]. |

[1] Mild intestinal lesions of 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 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 its local representative 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

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.

### 3.9 Administration routes and dosage

For oral administration to chickens by spray-on-feed, by spray-on-chickens, or in drinking water. A single dose of vaccine (0.004 ml undiluted vaccine) should be administered to chickens between day-old and 9 days of age, inclusive.

Shake the container vigorously for 30 seconds before use, to ensure homogeneous suspension of the oocysts.

*a) in drinking water*

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. Care should be taken to empty the vial completely by rinsing in the water used to dilute the vaccine, and the diluted vaccine should be 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 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.

IMPORTANT
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, diluted in water. The vaccine should be diluted in cold tap water to a concentration of 1 dose per 0.4 ml (1000 doses of vaccine added to 400 ml of water, 5000 doses of vaccine added to 2 litres of water). Care should be taken to empty the vial completely by rinsing them in the water used to dilute the vaccine and 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 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

I.e. for the preparation of 1000 doses diluted vaccine, a total of 0.21 × 1000 = 210 ml diluted vaccine is needed and is divided over the vaccine, solvent and water as below:

1. 4 ml vaccine (1 vial)
2. 100 ml Solvent (1 bottle)
3. Fill up to 210 ml with tap water

The solvent contains a 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. Use clean containers for vaccine preparation. Shake the 5000 dose (or 1000 dose) vial of the vaccine vigorously for 30 seconds to ensure re-suspension of the oocysts. Empty the content of the vial completely by rinsing with a small quantity of the water used to dilute the vaccine. Empty the content of the solvent bottle completely by rinsing with the remaining amount of water and mix to a uniform solution. Add the vaccine solution to the solvent solution 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.

### 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.

The vaccine 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.

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.

## 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 the 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:
PETG or PET vials closed with a bromobutyl stopper and sealed with an aluminium cap.

Pack sizes:
Box with 1 vial of vaccine containing 4 ml (1000 doses)
Box with 1 vial of vaccine 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, the vaccine is supplied together with the appropriate volume of solvent:

Pack sizes:
100 ml bottle of solvent (for 1000 doses)
500 ml bottle of solvent (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.

## 6. NAME OF THE MARKETING AUTHORISATION HOLDER

Intervet Ireland Limited

## 7. MARKETING AUTHORISATION NUMBER(S)

VPA10996/245/001

## 8. DATE OF FIRST AUTHORISATION

19/10/2007

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

30/10/2026

## 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).