RLP
APPROVED

Product Name: PARACOX -8 ANTICOCCIDIAL VACCINE FOR CHICKENS
APVMA Approval No: 61990/133555

Label Name:	PARACOX -8 ANTICOCCIDIAL VACCINE FOR CHICKENS

Signal Headings:	FOR ANIMAL TREATMENT ONLY

Constituent Statements:	Each dose of 0.004 ml vaccine contains the following numbers of live sporulated oocysts derived from eight precocious lines of coccidia: ≥ 500 oocysts EIMERIA ACERVULINA HP ≥ 100 oocysts EIMERIA BRUNETTI HP ≥ 200 oocysts EIMERIA MAXIMA CP ≥ 100 oocysts EIMERIA MAXIMA MFP ≥ 1000 oocysts EIMERIA MITIS HP ≥ 500 oocysts EIMERIA NECATRIX HP ≥ 100 oocysts EIMERIA PRAECOX HP ≥ 500 oocysts EIMERIA TENELLA HP

Claims:	As an aid in the control of coccidiosis in chickens caused by a variety of Eimeria species.

Net Contents:	1000 doses (4 mL) 5000 doses (20 mL) 5 x 1000 doses (5 x 4 mL) 5 x 5000 doses (5 x 20 mL)

Directions for Use:	

Restraints:	USE ONLY with the Solvent for Spray-on-Chickens (APVMA No. 92395) product for spray-on chickens administration. DO NOT USE in birds in lay.

Contraindications:	DO NOT administer in conjunction with other anticoccidial agents.

Precautions:	

Side Effects:	Overdosage: Severe overdose (x 5 or more) may lead to a temporary reduction in daily liveweight gain.

Dosage and Administration:	Shake the vial vigorously for 30 seconds before use to ensure homogeneous suspension of the oocysts. Use product immediately after broaching the vial. Vaccinate healthy animals only. Dose: A single dose of vaccine is administered to chickens from one day of age via spray-on chickens or spray-on feed or at 3-9 days old via drinking water. The nominal dose is 0.004 mL per chicken. Each 4 mL vial will provide sufficient vaccine for 1,000 chickens and each 20 mL container will provide sufficient vaccine for 5,000 chickens. Administration: Do not administer into header tanks. Clean drinkers and refill with water prior to adding vaccine. Do not apply vaccine into dry drinkers. (a) In drinking water: Drinking water should be withdrawn for 1-2 hours before vaccination. PARACOX-8 is administered in water via line drinkers from first placement of the chicks at 1 day of age. Place chicks in the house at day-old and encourage them to become accustomed to the drinking 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 2 hours before administration of the vaccine. At the same time the lighting is switched on. Drain each drinking line completely. The vaccine should be diluted to a concentration of 1 dose (0.004 mL) per 2 mL in cold tap water. Dilute the vaccine to a concentration of 1 dose/2 mL of cold tap water. Calculate the average number of birds per drinking line and calculate the volume needed per drinking line at a rate of 2 mL per bird. 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. For drinker lines temporarily connected up to a re-circulating system, it is recommended that the 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 birds are allowed to drink. Vaccination via pipeline nipple drinkers is only recommended when the vaccine solution can remain constantly agitated to avoid settling of the oocysts. Alternatively, vaccination using supplementary drinkers between 5-9 days may be preferred. It is a common practice on farms using nipple lines that 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 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.

	IMPORTANT – It is recommended that where nipple line drinkers are in use, temporary, supplementary drinkers should be provided for the purpose of administering the vaccine. It should be stressed that the birds should be fully accustomed to these drinkers before vaccination. 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 cold tap water. The vaccine should be diluted to a concentration of 1 dose per 0.4 mL in cold tap water. (1000 doses of PARACOX-8 added to 400 mL of water, 5000 doses of PARACOX-8 added to 2 litres of water). Care should be taken to empty the vial completely by rinsing 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 in a cabinet providing 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 of diluted vaccine, a total of 0.21 x 5000 = 1050 mL diluted vaccine is needed as it is divided over the vaccine, Solvent for Spray-on-Chickens (APVMA No. 92395) and tap water as below: 1. 20 mL PARACOX-8 vaccine (1 vial). 2. 500 mL Solvent for Spray-on-Chickens (1 bottle). 3. Fill-up to 1050 mL with tap water. i.e. for the preparation of 1000 doses of diluted vaccine, a total of 0.21 x 1000 = 210 mL diluted vaccine is needed and is divided over the vaccine, Solvent for Spray-on-Chickens (APVMA No. 92395) and water as below: 1. 4 mL PARACOX-8 vaccine (vial). 2. 100 mL Solvent for Spray-on-Chickens (1 bottle). 3. Fill up to 210 mL with tap water. The Solvent for Spray-on-Chickens (APVMA No. 92395) 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 (1000 dose) vial vigorously for 30 seconds to ensure re-suspension of the oocysts. Empty the contents of the vial completely by rinsing with a small quantity of water and mix to a uniform solution. Empty the contents 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 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.

General Directions:	PARACOX-8 vaccine will not protect species other than the chicken (Gallus gallus) against coccidiosis. In any animal population there may be a small number of individuals which fail to respond fully to vaccination. Successful vaccination depends upon correct storage and administration of the vaccine and the ability of the animal to respond. This can be influenced by such factors as genetic constitution, intercurrent infection, age, nutritional status, concurrent drug therapy and stress.

	PARACOX-8 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 or litter. This ensures satisfactory flock protection against all the pathogenic species of Eimeria that affect the chicken. Mild lesions of eg. E. acervulina, E. necatrix and E. tenella (lesion score of +1 or +2 using the numerical ranking system of Johnson & Reid (1970)) have occasionally been discovered in birds 3-4 weeks after vaccination. Transient reduction in some bird weight gains occurred up until 28 days after vaccination, with compensatory growth over the subsequent week noted in the local Australian trial. This effect was not found in the overseas trials. It is recommended to observe birds and increase feed appropriately if condition loss is noted. It is recommended that vaccinated birds remain on the same litter for the first 4 weeks after vaccination to establish full immunity. The effect of moving birds between facilities following vaccination has not been fully investigated. Local efficacy against Australian strains of E. acervulina, E. maxima, E. necatrix, E. praecox and E. tenella has been demonstrated using isolates from broiler breeder, grower and layer facilities in the five mainland states of Australia. Efficacy against all seven strains of chicken Eimeria has been demonstrated in UK and Europe. Interaction with other medicaments and other forms of interaction Food and water provided at any stage before or after vaccination must be free from anticoccidial agents including sulfonamides and antibacterial agents having anticoccidial activity. Since the protection against coccidial infection following PARACOX-8 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. General management Chickens should be healthy and reared on floor with litter. Ensure that all vaccination equipment is thoroughly cleaned before use. Litter should be removed and chicken housing thoroughly cleaned and disinfected between rearing cycles to minimise carry over to the next flock. This will reduce the chances of a coccidial field challenge occurring before the development of adequate flock protection.

Withholding Periods:	Zero (0) days.

Trade Advice:	

Safety Directions:	

First Aid Instructions:	If poisoning occurs, contact a doctor or Poisons Information Centre. Phone Australia 131126.

First Aid Warnings:	

Additional User Safety:	When spraying the vaccine, well fitting masks and eye protection should be worn. Additional information is listed in the safety data sheet.

Environmental Statements:	

Disposal:	Discard unused vaccine and empty vaccine vials into a disinfectant solution (eg. chlorine based bleach). Dispose of any such inactivated, unused vaccine and empty containers by wrapping in paper and putting in garbage.

Storage:	Store between 2°C and 8°C (refrigerate, do not freeze). Protect from light. Keep out of reach of children.