



Product Name: PARACOX-5 ANTICOCCIDIAL VACCINE FOR CHICKENS
APVMA Approval No: 62055/133582

Label Name:	PARACOX-5 ANTICOCCIDIAL VACCINE FOR CHICKENS
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Signal Headings:	FOR ANIMAL TREATMENT ONLY
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Constituent Statements:	<p>Each dose of 0.004 mL vaccine contains the following numbers of live sporulated oocysts derived from five precocious lines of coccidia:</p> <p>≥ 500 oocyst/dose EIMERIA ACERVULINA HP ≥ 200 oocyst/dose EIMERIA MAXIMA CP ≥ 100 oocyst/dose EIMERIA MAXIMA MFP ≥ 1000 oocyst/dose EIMERIA MITIS HP ≥ 500 oocyst/dose EIMERIA TENELLA HP</p>
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Claims:	Aids in the control of coccidiosis in broiler chickens caused by Eimeria acervulina, Eimeria maxima CP, Eimeria maxima MFP, Eimeria mitis and Eimeria tenella.
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Net Contents:	<p>1000 doses (4 mL) 5000 doses (20 mL) 5 x 1000 doses (5 x 4 mL) 5 x 5000 doses (5 x 20 mL)</p>
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Directions for Use:	
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Restrictions:	DO NOT USE in birds in lay.
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Contraindications:	DO NOT administer in conjunction with other anticoccidial agents.
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Precautions:	
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Side Effects:	<p>Overdosage: Repeat dosing or severe overdose may lead to a temporary reduction in daily liveweight gain.</p>
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Dosage and Administration:

SHAKE EACH VIAL OF VACCINE VIGOROUSLY FOR 30 SECONDS PRIOR TO DILUTION.

Use immediately on broaching.

When diluted with water, use all product within to 2 hrs of mixing.

When diluted with Solvent for Spray-on-Chickens, USE PRODUCT IMMEDIATELY AFTER MIXING.

Vaccinate healthy animals only.

Dosage

A single dose of vaccine is administered to chickens from one day of age via spray-on feed, spray-on chickens or at 3 days-old via drinking water. The nominal dose is 0.004 mL per chicken. Each 4 mL container will provide sufficient vaccine for 1,000 chickens and each 20 mL container will provide sufficient vaccine for 5,000 chickens.

Administration

Chickens should be floor reared on litter.

On-Feed

Do not administer vaccine via an automatic feeding machine or place treated feed directly under heating lamps.

Sufficient starter feed for the first 24-48 hours should be laid out on paper or plastic along the floor of the poultry house. Shake the container vigorously for 30 seconds before use, to ensure resuspension of oocysts. Dilute PARACOX-5 in water at the rate of approximately 5,000 doses in up to 3 litres of water and spray evenly over the surface of the feed using a coarse spray. Ensure controlled, even coverage of the total surface area of the feed available to the chicks. Agitate the applicator reservoir regularly throughout the 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 is diluted for use it should be sprayed onto feed and birds be placed with access to the feed within two hours.

In drinking water

Do not administer into header tanks.

Clean drinkers and refill with water prior to adding vaccine. Do not apply vaccine into dry drinkers.

Drinking water should be withdrawn for 1-2 hours before vaccination.

Vaccination via pipeline nipple drinkers is only recommended when the vaccine solution can remain constantly agitated to avoid settling of oocysts.

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.

Dilute the vaccine to a concentration of 1 dose/2- 4 mL of 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 of 2-4 mL per bird.

Fill each line with diluted vaccine and lower to allow the birds access to the drinking system. 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 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 drinkers at the end of the line before chicks are allowed to start drinking.

By spray-on-chickens

For administration by spray in the hatchery, a red food colouring agent Cochineal E120 should be added to the diluted vaccine, or the vaccine should be diluted with Solvent for Spray-on-Chickens (APVMA No. 92395)

For the spray-on chickens method of administration, a significant reduction in the efficacy may be observed if diluted in tap water only. The purity of cochineal E120 must be in compliance with the Commission Directive 95/45/EC, and is available from the manufacturer.

(a) Solvent for spray-on chickens

Vaccine should be delivered using a dose volume of between 0.21 mL 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 of 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 for Spray-on-Chickens (1 bottle)
3. Fill up to 1050 mL with tap water

Water used for vaccine dilution should be fresh, cool and free of pollution. The solvent contains a red colouring agent and xanthan gum, both for better uptake. The water is added to the bottle of solvent in order to rinse out the remaining solvent.

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 spray evenly over the birds using a coarse spray. Agitate the applicator reservoir regularly throughout the application to avoid settling out of oocysts. 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, Cochineal E120

Vaccine should be delivered using a dose volume of between 0.21 mL 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 to 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 colour (Cochineal E120) to the water to give a concentration of 0.1%w/v.

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 chickens. Agitate the applicator reservoir regularly throughout the 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:

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 sulphonamides and anti-bacterial agents having anticoccidial activity.

	<p>Since immunity to coccidial infection following PARACOX-5 administration is enhanced by natural challenge, it should be noted that access to any agents having anti-coccidial activity at any time following vaccination may reduce the duration of effective protection. This is particularly important in the four weeks following vaccination.</p> <p>To reduce the chance of a coccidial field challenge occurring before the onset of immunity, litter should be removed and housing thoroughly cleaned between rearing cycles.</p> <p>General management</p> <p>Ensure that all vaccination equipment is thoroughly cleaned before use.</p> <p>Litter should be removed and chicken housing thoroughly cleaned and disinfected between rearing cycles. This will reduce the chance of a coccidial field challenge occurring before the development of adequate flock protection.</p> <p>Once the vaccine has been diluted for use it should either be used immediately in a spray cabinet in the hatchery, or sprayed onto feed and birds placed with access to the feed within two hours, or added to drinking lines and the birds given access to drinkers immediately.</p> <p>Partially used containers and diluted vaccine must be discarded immediately following one vaccination session, as under field conditions it may be difficult to avoid accidental contamination of the vaccine.</p>
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Withholding Periods:	Zero (0) days.
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Trade Advice:	
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Safety Directions:	
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First Aid Instructions:	If poisoning occurs, contact a doctor or Poisons Information Centre. Phone Australia 131126.
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First Aid Warnings:	
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Additional User Safety:	<p>When spraying the vaccine, well-fitting masks and eye protection should be worn.</p> <p>Additional information is listed in the safety data sheet.</p>
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Environmental Statements:	
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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.
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Storage:	Store between 2°C to 8°C (refrigerate, do not freeze). Protect from light. Keep out of reach of children.
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