

PARACOX[®]-8

Anticoccidial Vaccine for Chickens

ACTIVE CONSTITUENTS:

Eimeria acervulina HP ≥500 oocysts/dose, *Eimeria brunetti* HP ≥100 oocysts/dose, *Eimeria maxima* CP ≥200 oocysts/dose, *Eimeria maxima* MFP ≥100 oocysts/dose, *Eimeria mitis* HP ≥1000 oocysts/dose, *Eimeria necatrix* HP ≥500 oocysts/dose, *Eimeria praecox* HP ≥100 oocysts/dose and *Eimeria tenella* HP ≥500 oocysts/dose.

PARACOX is indicated as an aid in the control of coccidiosis in chickens caused by a variety of *Eimeria* species.

PARACOX 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 vaccine contains live coccidia and is dependant 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.

DIRECTIONS FOR USE**Contraindications**

DO NOT administer in conjunction with other anticoccidial agents.

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.

Only healthy birds are to be vaccinated.

Dosage and administration

100 mL Sachet contains 1000 doses. 500 mL Sachet contains 5000 doses.

Dose: A single dose of vaccine is administered to chickens at either day-old in the hatchery by spray or at day-old via feed or at 3-9 days-old via water. The nominal dose is 0.1 mL per chicken.

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:**SHAKE AND MASSAGE SACHET VIGOROUSLY FOR 30 SECONDS BEFORE USING.**

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.

Administration:

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.

It is necessary to shake and massage the sachet vigorously for 30 seconds before use to ensure homogeneous suspension of the oocysts.

PARACOX contains xanthan gum which will aid the suspension of oocysts in the water providing it is used within the recommendations made below:

(a) In water:

PARACOX is administered into individual drinkers.

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 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 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.

Automatic Circular Drinkers (Bell-type):

Raise drinkers 1-2 hours before vaccination.

Ensure drinkers are clean and adjust valve 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. Ensure that there are between 100 and 250 birds per drinker. Water supply to the drinkers should not be turned off during vaccination, ie. 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.

Trough Drinkers:

Method is essentially similar to that for Bell-type drinkers. Drain or remove drinkers 1-2 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 1-2 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.

“Supplementary” drinkers:

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 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. The vaccine should be diluted no more than 1/50.

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, 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-8 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) Hatchery Spray:

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 cabinet 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). 5000 doses are presented in a 500 mL pack (1000 doses in a 100 mL pack). Subtract 500 mL (100 mL) from the total volume calculated and add this volume of water to a suitable container (for a 21 mL dispensing volume this should be 550 mL for 5000 doses or 110 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.

Shake and massage the 5000 dose (1000 dose) sachet vigorously for 30 seconds to ensure re-suspension of the oocysts. Add the entire contents of the sachet to the water 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. Prepare birds for delivery to rearing accommodation.

WITHHOLDING PERIODS: Zero (0) days.

General directions

A significant reduction in efficacy may be observed if the red food colouring agent cochineal E120 is not added to the diluted vaccine before administration via hatchery spray. Addition of cochineal E120 is only to be employed for hatchery spray administration. Full efficacy of the product may not be achieved unless cochineal E120 food colouring agent is used. Food given to chickens vaccinated with PARACOX vaccine **must not** contain anticoccidial agents (before or after vaccination). Chickens should be healthy and floor-reared on deep 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. This will reduce the chances of a coccidial field challenge occurring before the development of adequate flock protection.

Interaction with other medicaments and other forms of interaction:

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

Since the protection against coccidial infection following PARACOX 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.

Undesirable Effects, Frequency and Seriousness:

None when used as recommended.

Overdosage:

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

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.

For further information contact MSD Animal Health Customer Service on 1800 033 461.

FIRST AID

If poisoning occurs, contact a doctor or Poisons Information Centre. Phone Australia 131126, New Zealand 0800 POISON (0800 764 766).

Additional information is listed in the safety data sheet.

DISPOSAL

Discard unused vaccine and empty vaccine sachets 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.

Warranty

Intervet Australia Pty Limited (IAPL), trading as MSD Animal Health, warrants that this product is of merchantable quality and fit for its intended purpose. IAPL's liability for any loss, including consequential losses or injury caused by act or omission, including negligent acts or omissions, by IAPL or its agent, is limited to replacing or repairing the product at the option of IAPL. If possible, a sample of any product causing concern should be retained or delivered to IAPL within 30 days for a scientific examination.

APVMA Approval No.: 61990/0609

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New Zealand Information

By law the user must take due care, obtaining expert advice when necessary, to avoid unnecessary pain and distress when using the product other than as directed on the label.

ACVM Registration No. A006465

See www.foodsafety.govt.nz for registration conditions.

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