FOR ANIMAL USE ONLY

PARACOX®

Reg. No. G1994 (Act 36/1947)

Namibia Reg. No. V01/24.3/517 NS0

Attenuated Oral Coccidiosis Vaccine for Chickens

This vaccine may only be used by or under the supervision of persons registered in terms of or authorised in terms of section 23 (1) (c) of the Veterinary and Para-Veterinary Professions Act, 1982 (Act 19 of 1982).

INDICATIONS

For the active immunisation of chickens against *Eimeria acervulina*, *E. brunetti*, *E. maxima*, *E. mitis*, *E. necatrix*, *E. praecox* and *E. tenella*.

COMPOSITION

Paracox[®] is a translucent, viscous suspension of oocysts derived from 8 precocious lines of coccidia, presented as a live, attenuated, oral vaccine.

STORAGE

- Store between 2 °C and 8 °C.
- Do not freeze.
- Protect from light.

WARNINGS

- Withdrawal period: None.
- Vaccinate healthy chickens only.
- Freezing this vaccine will inactivate it. Do not under any circumstances use this vaccine
 if it has been frozen.
- Food and water provided at any stage before or after vaccination must be free from anticoccidial agents including sulphonamides as well as antibacterial agents that have anticoccidial activity (viz. oxytetracycline, chlortetracycline, furazolidone, nitrofurazone).
- Since immunity to coccidial infection following **Paracox**® administration is enhanced by natural challenge, it should be noted that access to any agents with anticoccidial activity at any time following vaccination may reduce the duration of effective immunity.
- The vaccine will not actively immunise avian species other than the chicken against coccidiosis.
- Use before expiry date on carton.
- Partially used sachets of the vaccine must be discarded immediately following 1 dosing session. Empty and partially used sachets should be disposed of as per local waste disposal regulations.
- KEEP OUT OF REACH OF CHILDREN, UNINFORMED PERSONS AND ANIMALS.
- Although this vaccine has been extensively tested under a large variety of conditions, failure thereof may ensue as a result of a wide range of reasons. If this is suspected, seek veterinary advice and notify the registration holder.

PRECAUTIONS

- For oral administration only from 1 day of age by hatchery spray in conjunction with added red colouring agent, or by drinking water from 5 to 9 days old.
- Do not administer to dry drinkers.
- Do not administer into header tanks.
- To reduce the chances of coccidial field challenge occurring before the full development of immunity, chicken housing should be thoroughly cleaned between rearing cycles.
- A reduction in efficacy may be observed if a red food colouring agent cochineal E120 is not added to the diluted vaccine before administration by hatchery spray. Addition of a red food coloring agent cochineal red is only to be employed for hatchery spray administration. The recommended colouring agent is cochineal E120 and full efficacy of the product may not be achieved if an alternative to cochineal E120 food colouring agent is used.

DOSAGE AND DIRECTIONS FOR USE - USE ONLY AS DIRECTED

The minimum dose of vaccine is 0,1 ml per chicken. Each 100 ml sachet will provide sufficient vaccine for 1 000 chickens and each 500 ml sachet will provide sufficient vaccine for 5 000 chickens.

Paracox® is for oral administration to chickens from 1 day of age by spray on feed or by hatchery spray, or by drinking water from 5 to 9 days old.

In water

For oral administration in drinking water.

Chickens should be healthy and floor-reared and at least 5 to 9 days old.

A single dose is given between 5 days and 9 days of age, inclusive.

Ensure that all vaccination equipment is thoroughly cleaned before use.

Drinking water should be withdrawn 1 to 2 hours before vaccination depending on ambient temperature.

The vaccine should be thoroughly mixed before use by vigorous agitation of the sachet. Vaccine should not be administered into the header tank.

Supplementary drinkers

Paracox® may be administered into individual drinkers. The chicks must be fully accustomed to these drinkers before vaccination. Occasionally on farms using nipple lines, supplementary drinkers are provided for the first 4 to 5 days. These may be font-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 chicks of water for 1 to 2 hours before vaccination. In this case it may be appropriate to make an initial dilution of the vaccine in a suitable container, e.g. a watering can, and pour the diluted vaccine into each drinker, as for individual fonts.

A single dose is given between 5 and 9 days of age, inclusive.

The appropriate amount of vaccine for inoculation into each drinker is calculated as follows:

Total number of chickens per house (or pen) X 0,1 = Amount of vaccine (ml) per drinker Total number of drinkers per house (or pen)

The vaccine is delivered into each drinker through a short 19-gauge (1,10 mm) cannula attached to an automatic syringe.

A suitable cannula is included with each 100 ml and 500 ml pack of Paracox®.

The syringe should be held at an oblique angle to the surface of the water and moved around the drinker during delivery in order to ensure even distribution of the vaccine.

Bell drinkers: Raise drinkers 1 to 2 hours before vaccination depending on the ambient temperature. Do not drain. Inoculate appropriate volume of vaccine into each drinker and lower immediately

Trough drinkers: Drain 1 to 2 hours before vaccination depending on the ambient temperature. Allow to refill immediately before inoculation of the appropriate amount of vaccine.

Hand-filled, fountain type: Remove 1 to 2 hours before vaccination depending on the ambient temperature. Fill prior to inoculation of the appropriate amount of vaccine, and return drinkers to the house (pen).

Hand-filled, supplementary drinkers: Withdraw drinkers 1 to 2 hours before vaccination depending on the ambient temperature. Make a dilution of vaccine in a suitable vessel e.g. clean watering can and pour diluted vaccine into each drinker. The dilution should be no more than 1:50.

Hatchery spray

For administration by spray in the hatchery the recommended red food colouring agent cochineal E120, should be added to the diluted vaccine to give a concentration in the diluted vaccine of 0,1 % *w/v*, equivalent to 210 to 280 mcg/chick. The purity of the cochineal must be in compliance with the Foodstuffs, Cosmetics and Disinfectants Act (Act No. 54 of 1972). Vaccine should be delivered using a dose volume of 0,21 m² of diluted vaccine per chick in a cabinet (Spraycox or as approved by MSD Animal Health) 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 5 000 doses (or by 10 for 1 000 doses). 5 000 Doses are presented in a 500 m² pack (1 000 doses in a 100 m² pack). Subtract 500 m² (or 100 m²) from the total volume calculated and add this volume of water to a suitable container (for a 21 m² dispensing volume this should be 550 m² for 5 000 doses or 110 m² for 1 000 doses).

Uptake of the vaccine by the chicks, 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 5 000 dose (or 1 000 dose) sachet vigorously for 30 seconds to ensure resuspension 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 chicks 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 chicks for delivery to rearing accommodation.

About the pack

No vent needle is needed with this all-plastic pack. The contents will remain sterile and cannot be tampered with until opened with the probe attached to the delivery tube.

How to use the pack

- 1. Attach open end of delivery tube to automatic syringe.
- 2. Centre the plastic probe (affixed to the delivery tube) on to the circular stud at the base of the container.
- 3. Using sharp, firm pressure, force the probe straight through the operating position within the stud.

A small amount of extra vaccine is added to each pack to allow for priming of the syringe.

PRESENTATION

Sachets containing 100 ml (1 000 doses) or 500 ml (5 000 doses).

REGISTRATION HOLDER

Intervet South Africa (Pty) Ltd. 20 Spartan Road, Spartan 1619, RSA Tel: +27 (0) 11 923 9300

Fax: +27 (0) 11 392 3158 www.msd-animal-health.co.za

MANUFACTURER

Intervet UK Ltd. Walton Manor, Walton Milton Keynes Bucks, MK7 7AJ, UK

DATE OF PUBLICATION OF THIS PACKAGE INSERT

12 March 2010

Zimbabwe Reg. No. 94/80.23.17/9372 Pharmacological classification: 802317

Distribution category: VMGD