FOR ANIMAL TREATMENT ONLY

EIMERIAVAX™ TAMM

Active Constituents: This vaccine contains viable oocysts of *Eimeria acervulina* Strain RA_{3+20}, *E. maxima* Strain MCK_{+10}, *E. mitis* Strain $Jormit_{3+9}$ *and E. tenella* Strain Rt_{3+15} suspended in phosphate buffered saline (PBS). Each dose comprises a minimum of *E. acervulina* 50 oocysts, *E. maxima* 100 oocysts, *E. mitis* 100 oocysts and *E. tenella* 150 oocysts, with a minimum predicted titre of 1.6×10^4 oocysts per mL (1000 dose) or 8.0×10^4 oocysts per mL (5000 dose) at the end of the shelf-life.

Statement of Claims: Live oocyst preparation to aid in the control of four major species of *Eimeria* that cause Coccidiosis in breeder, broiler and layer chickens in Australia.

1000 or 5000 Doses

Contents: 1000 or 5000 doses in a plastic vial. The *Eimeria* oocysts are supplied as a suspension of oocysts in PBS. Suspensions are contained within a single capped bottle accessed by removing the top foil cap and bung, and using an appropriate administration device, as required.

READ DIRECTIONS CAREFULLY

DIRECTIONS FOR USE

Contraindications:

- This product is contraindicated for vaccinating unhealthy birds.

Precautions:

- Avoid using in-feed or water anticoccidial medications at or soon after the time of vaccination, unless controlling clinical coccidiosis.
- Avoid administration of sulfa drugs immediately following vaccination with EIMERIAVAX™ TAMM as this may delay oocyst output and impair immune response.
- Avoid vaccinating with EIMERIAVAX™ TAMM unless birds are protected from exposure to litter from the previous batch for up to 14 days post-vaccination.
- Avoid using EIMERIAVAX™ TAMM as a diluent for other medications or treatments.
- Avoid using in birds in lay.

Dosage and Administration:

USE ALL PRODUCT WITHIN 24 HOURS AFTER OPENING.
Birds from day-old can be vaccinated with EIMERIAVAX™ TAMM. With individual bird administration, it is essential for each bird to receive a full dose.
A second dose should be administered if the first is not fully absorbed by the eye.
It is recommended that all birds be vaccinated prior to 18 weeks of age. The most appropriate age to vaccinate may be determined from knowledge of the challenge conditions applicable to the flocks concerned.
The effect of EIMERIAVAX™ TAMM vaccination during lay has not been assessed.

Method of Vaccination:

Preparation of vaccine for administration via eye-drop (1000 dose format only):

- Fully resuspend all oocysts by completely inverting the vaccine bottle back and forth 20 times before removing the capping.
- Insert the eye-dropper tip provided, or other calibrated administration device to deliver 25µL per drop of vaccine.
- Hold each bird with its head tilted to one side.
- If using a dropper tip attached to the bottle, invert the dropper allowing a single drop to form at the tip and fall freely into the open eye, gently flooding it. The drop (before release) and dropper tip or administration device should NOT touch the eye surface.
- Allow the bird to blink before releasing it.
- Administer a second drop if the bird did not receive a full dose.
- Eye-drop administration of the 5000 dose presentation is not recommended.

Preparation of vaccine for spray-on-bird administration (1000 or 5000 doses):

EIMERIAVAX™ TAMM has been demonstrated effective when administered using a hatchery spray apparatus that delivers 24 mL of diluted vaccine per box of 100 day-old chicks, i.e. 0.24 mL per chick. Please note the following points:

- Fully resuspend all oocysts by completely inverting the vaccine bottle back and forth 20 times before removing the capping.
- Open the vaccine bottle when required by peeling back the foil cap and removing the rubber bung.
- One bottle of EIMERIAVAX™ TAMM (1000 dose) is diluted with water or a compatible spray additive (if used) to a total volume of 240 mL. This is sufficient to treat 10 x 100-chick boxes
- Alternatively, one bottle of EIMERIAVAX™ TAMM (5000 dose) is diluted to a total volume of 1200 mL, which is sufficient to treat 50 x 100-chick boxes.
- Rinse the vaccine bottle several times with water and add to the prepared vaccine mixture to ensure all the oocysts are removed from the bottle before adjusting to the total volume.
- Ensure the diluted vaccine is regularly agitated during the spray application period to ensure vaccine oocysts do not settle.
- The spray unit should deliver an even-sized droplet, and complete box coverage with the compatible blue dye or additive (if used) evident.
- After spraying, leave the chicks in bright light to allow preening and vaccine ingestion.
- Please contact Bioproperties if further information regarding specific spray units is required.

Preparation of vaccine for spray-on-feed administration (1000 or 5000 doses):

- Distribute a sufficient amount of starter feed for the chick's first 12-24 hours on paper or plastic along the floor of the poultry house in the brooding area.
- Fully resuspend all oocysts by completely inverting the vaccine bottle back and forth 20 times before removing the capping.
- Dilute the vaccine in water at the rate of 1000 doses in 200 mL (layer-type birds), or 600 mL (meat-type birds).
- To ensure that all oocysts are removed from the vial, rinse it out 2-3 times with the vaccine water.
- Spray the oocyst suspension evenly over the surface of the feed using a coarse-spray nap-sack. Ensure a controlled even coverage of the total surface area of the feed available to chickens.
- Agitate the applicator reservoir regularly throughout the spraying period to avoid sedimentation 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 has been diluted for use, it should be sprayed immediately onto feed and birds should be placed with access to the feed immediately after distributing the vaccine.
- When the application of treated–feed has been consumed, routine feeding may continue.

Preparation of vaccine for drinking water administration (1000 or 5000 doses):

- Ensure there are sufficient Bell-type drinkers for the number of birds to be vaccinated (1:50-1:100), and the drinkers are placed evenly throughout the brooding area.
- All chicks must have access to the vaccine-water and only medicated water is provided during the vaccination period.

- Ensure water is withheld for 2 - 4 hours prior to vaccination.

Prepare the vaccine suspension as follows:

- Fully resuspend all oocysts by completely inverting the vaccine bottle back and forth 20 times before removing the capping.
- Pour the whole contents of each vial into a clean vessel containing drinking water at room temperature, and of sufficient volume expected to be consumed within a 2-3hr period (note: for day-old chicks this equates to approximately 5mL per chick).
- Rinse the vial 2-3 times to ensure that all of the oocysts have been transferred to the vaccine preparation vessel.
- Evenly distribute the vaccine water between the available drinkers.
- Ensure the lights are on bright during the vaccine administration period, and walk the birds regularly to encourage them to move toward the drinkers
- Note: xanthum gum may be added to the vaccine suspension prior to distribution into the drinkers to aid suspension of the oocysts. The gum powder should be added at the rate of 1g/ L of final vaccine suspension (made as 5g into 3L water, then mixed with 2L of vaccine suspension / 1000 doses).

Bird Management After Administration

- Continued exposure to daughter oocysts shed in the faeces of vaccinated birds is essential for the development of an effective immune response.
- It is recommended that birds should be contained in the brooding area where vaccination occurred for up to 2 weeks after vaccination. Where they need to be released to a larger area within 2 weeks, the expansion should occur within 5 days post-vaccination so the daughter oocysts are excreted over the larger area and all birds will have access to support re-infection.
- **Birds housed in cages:** These birds should be vaccinated a minimum of 14 days before being transferred onto litter or into a slat-floored shed.
- **Birds reared on litter:** These birds can be vaccinated from day-old. Anticoccidial medication is never recommended unless clinical coccidiosis from wild field strains is affecting bird performance. In these instances, the manufacturer's recommendations for the medication program are to be followed.
- If depression associated with vaccination is noted, light intensity should be increased and/or extended and extra feed provided.
- Monitor flocks closely for 4 weeks post-vaccination. Some gross intestinal lesions can be expected on post-mortem examination. These lesions can be associated with an immune response and should not be used as the sole criterion for assessing vaccine efficacy.
- Investigate all suspect coccidiosis lesions as this vaccine does not protect against *Eimeria* species that are not represented in the vaccine.

Duration of immunity: An effective immune response can be expected for at least 18 weeks post-vaccination. Continuing exposure to oocysts in the environment is essential and provides ongoing stimulus to the immune system. Under these conditions, a protective immune response beyond 18 weeks of age can be expected. When birds are removed from the source of vaccine oocysts, such as when they are transferred between facilities, immunity may wane due to reduced exposure to cycling oocysts. As a result, birds may subsequently become susceptible to field infections from *Eimeria* species represented in the vaccine.

WITHHOLDING PERIODS: Zero (0) days

USER SAFETY INFORMATION:

Accidental contact of EIMERIAVAX^{TM} TAMM with eyes or mouth may cause irritation. Eyes should be rinsed immediately and medical advice sought. The mouth should be rinsed two or three times with a mouth gargle.
Additional information is available on the product Safety Data Sheet.

FIRST AID:

If poisoning occurs, contact a Doctor or Poisons Information Centre on 13 11 26.

DISPOSAL:

Discard unused vaccine and empty vaccine bottles into a disinfectant solution (e.g. chlorine based bleach). Dispose of any such inactivated, unused vaccine and empty containers by wrapping in paper and putting in garbage.
In cases of spillage, soak up the liquid with an absorbent sponge or cloth and incinerate. Treat the surface with a disinfectant solution (e.g. chlorine based bleach).

CAUTION:

The capability of this vaccine to produce satisfactory results depends upon many factors including, but not limited to, conditions of storage and handling by the user, administration of the vaccine, health and responsiveness of individual birds and degree of field exposure. Therefore, directions for use should be followed carefully.

CONTACT DETAILS:

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BIOPROPERTIES Pty Ltd
Eimeria Pty Ltd

STORAGE INSTRUCTIONS:

Product should be stored between 2^{o}C and 8^{o}C (Refrigerate. Do not freeze) until required.
Product should be used by the expiry date.

WARRANTY AND DISCLAIMER

BIOPROPERTIES Pty Ltd manufactures, markets and sells EIMERIAVAX^{TM} TAMM on behalf of Eimeria Pty Ltd.
EIMERIAVAX^{TM} TAMM has been tested and meets safety and potency standards according to the Standards required by APVMA.
BIOPROPERTIES Pty Ltd and Eimeria Pty Ltd accept no responsibility for events arising from the misuse or mishandling of the product. BIOPROPERTIES Pty Ltd and Eimeria Pty Ltd give no warranty (express or implied) with respect to the product, including without limitation any warranty as to completeness, merchantability or fitness for a particular purpose. Under no circumstances shall BIOPROPERTIES Pty Ltd or Eimeria Pty Ltd be liable for indirect, special, consequential or punitive damages.

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