

FOR ANIMAL TREATMENT ONLY

Vaxsafe[®] MG Vaccine (living)

Active Constituent: Each dose contains $\geq 10^{7.0}$ CCU* living, attenuated, temperature-sensitive *Mycoplasma gallisepticum* vaccine Strain ts-11.

* Colour Changing Units

Statement of Claims: An aid in the control of chronic respiratory disease (CRD) caused by *M. gallisepticum* (MG) in susceptible (MG free) chickens at risk of infection.

Susceptible (MG free) layer flocks vaccinated with Vaxsafe MG vaccine prior to MG challenge exhibit less respiratory disease, require less anti-microbial medication and during lay will produce more eggs than comparably challenged non-vaccinated flocks. Safety testing has shown *M. gallisepticum* Strain ts-11 to be virtually non-pathogenic in chickens and not readily transmitted between birds.

2000 Doses

Contents: Vaxsafe MG is supplied frozen in a plastic peel-top eye-dropper vial containing 30 mL vaccine, sufficient for 2000 doses by eye drop application.

READ DIRECTIONS CAREFULLY

DIRECTIONS FOR USE:

Contraindications:

- This product is contraindicated for vaccinating unhealthy birds.
- This product is contraindicated for vaccination of birds undergoing medication with an antimicrobial known to inhibit *M. gallisepticum* multiplication, eg, Tetracycline, Tiamulin, Tylosin, Enrofloxacin, Lincospectin, Gentamycin or macrolide antibiotics.

Precautions:

- Vaxsafe MG contains live organisms and correct storage and administration are essential for successful use.
- Do not refreeze Vaxsafe MG after thawing.
- Withdraw antibiotics from the flock for a period equivalent to the recommended withholding period prior to vaccination and do not use after vaccination.
- Where antibiotics must be used, preference should be given to agents with low mycoplasma activity such as penicillin, amoxycillin or neomycin. They should not be given within 4 weeks after vaccination.
- Do not dilute. Thawed vaccine should be used as supplied.

Dosage and Administration:

- Pullets are normally vaccinated between 6-14 weeks of age with the minimum age for efficacious use being 4 weeks.
- Application is by eye drop.
- All birds in the flock should be vaccinated.
- Vaccination need only be done once. Revaccination is not necessary and is not recommended.

General Instructions:

- Pullets should first be tested for MG infection. Testing for the presence of MG in the flock is normally by way of the rapid serum agglutination test (RSAT) with blood samples being tested within 24 hours of collection.
- Operators should contact their laboratory service for advice on the collection and number of blood samples to be taken.
- Only flocks with no antibodies to MG should be vaccinated. Vaccination of infected birds will not provide any economic benefit.
- Vaccination should be carried out on MG free birds at least 3 weeks before exposure to virulent MG is likely to occur.
- Vaccination can be timed to coincide with other flock management practices (e.g. beak trimming, Vaxsafe MS (*Mycoplasma synoviae*) and fowl pox vaccination).

Method of Vaccination:

- Thaw unopened vials rapidly in a large (5 – 10 L) volume of warm (35°C) water and use within 1 hour after thawing. Mix the contents of the vial by gentle agitation during thawing. Invert the bottle repeatedly following thawing to ensure the contents have resuspended.
- If held at room temperature, use the entire contents immediately.
- Remove the aluminium seal and rubber stopper before using a supplied plastic dropper tip, or other administration device that has been calibrated to distribute a 15 microlitre 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 bottle.
- Allow 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.

WITHHOLDING PERIOD: Zero (0) days

USER SAFETY INFORMATION:

If vaccine is accidentally splashed into the operator's eyes, the eyes and face should be thoroughly washed with water to avoid any potential reaction to culture medium constituents. 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.

STORAGE INSTRUCTIONS:

Vaxsafe MG should always be protected from direct sunlight. For long term storage Vaxsafe MG should be stored at or below -70°C. For short term storage (maximum of 4 weeks) Vaxsafe MG can be stored in a domestic chest freezer (at or below -18°C).

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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WARRANTY AND DISCLAIMER

Vaxsafe MG has been tested and meets safety and potency standards according to the Standards required by the APVMA. BIOPROPERTIES Pty Ltd accepts no responsibility for events arising from the misuse or mishandling of the product. BIOPROPERTIES Pty Ltd gives 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 be liable for indirect, special, consequential or punitive damages.

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