

FOR ANIMAL TREATMENT ONLY

Vaxsafe[®] MG304

Active Constituent: Each dose contains $\geq 10^{5.7}$ CCU* living, attenuated, temperature-sensitive *Mycoplasma gallisepticum* vaccine Strain ts-304.

* 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.

1000 / 2000 Doses

Contents: Vaxsafe MG304 is supplied as a freeze-dried plug containing at least 1000 / 2000 doses of product in a 10 mL glass vial with a rubber stopper.

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, e.g., Tetracyclines, Tiamulin, Tylosin, Enrofloxacin, Lincomycin, Florfenicol, Gentamycin or macrolide antibiotics.
- This product is contraindicated for use with a) inactivated *M. gallisepticum* and b) other live *M. gallisepticum* vaccines.

Precautions:

- Vaxsafe MG304 contains live organisms and correct storage, and administration is essential for successful use.
- 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 or amoxicillin.
- Antibiotics should not be given within 4 weeks after vaccination.

Dosage and Administration:

- The minimum age for efficacious use is 3 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:

- Chickens should first be tested for MG infection. Testing for the presence of MG in the flock is normally by way of serum antibodies to MG in an ELISA or RSAT test with serum from 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 or PCR test negative should be vaccinated. Vaccination of birds infected with wild-type MG will not provide any economic benefit.
- Vaccination should be carried out on MG-free birds at least 4 weeks before exposure to virulent MG is likely to occur.
- The use of sterile equipment and proper technique is critical to avoid contamination of Vaxsafe MG304.
- Reconstituted vaccine must not be re-frozen.
- Use the reconstituted vaccine within 4 hours of first broaching the vial. Discard unused vaccine after this period.
- Administer only as directed.
- Vaccinate all birds in a flock at one time.
- Administer a full dose to each bird.
- Use entire contents of vial when first opened.
- Good husbandry practice and careful attention to techniques of administration are required.

Preparation of Vaccine for Eye drop Administration:

- Shake well before use, after liquid is added.
- The vaccine is supplied as a freeze-dried plug in a 10 mL glass vial. This must be reconstituted into a liquid diluent before use.
- Vaxsafe MG304 can be reconstituted in sterile diluent or in thawed Vaxsafe MS vaccine.
- 30 mL of diluent and 1 x 30 mL dropper bottle is required for each 1000 doses of vaccine.
- 60 mL of diluent and 2 x 30 mL dropper bottles are required for each 2000 doses of vaccine.
- Use sterile needles, syringes, and other equipment to avoid contamination of the product.
- An appropriately sized, sterile measuring container to measure the diluent volume is required.
- Dropper tips and dropper tip bottles (30 mL) are needed to administer a single eye drop dose of ~30 microlitres (µL).

Reconstitution in sterile diluent:

Sterile diluent for vaccine preparation and administration is available in separate pack sizes for reconstitution of Vaxsafe MG304.

If a 1000 dose vial vaccine is to be reconstituted use 30 mL diluent,

- Remove the central part of the crimp from the vaccine vial.
- Use the 30 mL diluent in plastic dropper bottle.
- Using a sterile syringe and needle, withdraw approximately 3 mL of diluent.
- Reconstitute the vaccine by gently injecting the contents of the syringe through the vial stopper. The small vacuum in the vial will allow the contents of the diluent to be drawn into the vial.
- Gently swirl to mix the reconstituted freeze-dried pellet.
- Transfer the reconstituted vaccine into the diluent bottle, ensuring all vaccine is removed from the vial.
- Rinse the vial with a further 3 mL or more of reconstituted vaccine if necessary.
- Fit the dropper tip to the dropper tip bottles to deliver 30 µL per drop.
- Gently shake the reconstituted vaccine to mix the vaccine.
- Use the entire contents within 4 hours after reconstitution.
- Hold each bird with its head tilted to one side.
- Deliver a single eye drop dose of ~30 microlitres (µL) using the dropper tip, supplied with the vaccine, into the open eye gently flooding it. The drop (before release) should NOT touch the eye surface.
- Allow the bird to blink before releasing it.

If a 2000 dose vial is to be reconstituted, use 60mL sterile diluent,

- Remove the central part of the crimp from the vaccine vial.
- Use 2 x 30 mL diluent in 2 x plastic dropper tip bottles.
- Add all 60 mL of diluent into a sterile container.
- Using a sterile syringe and needle, withdraw approximately 3 mL of diluent.
- Reconstitute the vaccine by gently injecting the contents of the syringe through the vial stopper. The small vacuum in the vial will allow the contents of the diluent to be drawn into the vial.
- Gently swirl to mix the reconstituted freeze-dried pellet.
- Transfer the reconstituted vaccine into the 60 mL diluent container, ensuring that all vaccine is removed from the vial.
- Rinse the vial with a further 3 mL or more of reconstituted vaccine if necessary.
- Gently shake the reconstituted vaccine to mix the vaccine.
- Transfer the reconstituted vaccine (60 mL) into original 2 x 30 mL dropper tip bottles, ensuring that all vaccine is removed from the container.
- Fit the dropper tip to the dropper tip bottles to deliver 30µL per drop.
- Use the entire contents within 4 hours after reconstitution. Do not freeze the reconstituted vaccine.
- Hold each bird with its head tilted to one side.
- Deliver a single eye drop dose of ~30 microlitres (µL) using the dropper tip, supplied with the vaccine, into the open eye gently flooding it. The drop (before release) should NOT touch the eye surface.
- Allow the bird to blink before releasing it.

Reconstitution with Vaxsafe MS vaccine:

If a 1000 dose vial vaccine is to be reconstituted in Vaxsafe MS (APVMA product number 47985),

- Use a 1000 dose presentation of Vaxsafe MS vaccine available as a wet frozen format in a 30 mL bottle.
- Thaw an unopened 1000 dose bottle of Vaxsafe MS vaccine rapidly in a large (5 – 10 L) volume of warm (35-37°C) water. Mix the contents of the vial by gentle agitation during thawing. Invert the bottle repeatedly following thawing to ensure there are no ice plugs remaining.
- Remove the central part of the crimp from the vaccine vials.
- Using a sterile syringe and needle, withdraw around 3 mL of thawed Vaxsafe MS vaccine.
- Reconstitute the freeze-dried pellet of the MG304 vaccine by gently injecting the contents of the syringe through the vial stopper. The small vacuum in the vial will allow the contents of the diluent to be drawn into the vial.
- Gently swirl to mix the reconstituted freeze-dried pellet.
- Transfer the reconstituted vaccine into the thawed Vaxsafe MS bottle, ensuring that all vaccine is removed from the vial.
- Rinse the vial with a further 3 mL or more of reconstituted vaccine if necessary.
- Fit the dropper tip to the dropper tip bottles to deliver 30 µL per drop.
- Gently shake the reconstituted vaccine to mix the vaccine.
- Use the entire contents within 4 hours after reconstitution.
- Hold each bird with its head tilted to one side.
- Deliver a single eye drop dose of ~30 microlitres (µL), using the dropper tip supplied with the vaccine, into the open eye gently flooding it. The drop (before release) should NOT touch the eye surface. Allow the bird to blink before releasing it.

If a 2000 dose vial vaccine is to be reconstituted in Vaxsafe MS (APVMA product number 47985),

- Use a 2000 dose presentation of Vaxsafe MS vaccine available as a wet frozen format in a 30 mL bottle and 1 x 30 mL diluent in a 30 mL plastic dropper tip bottle.
- Thaw an unopened 2000 dose bottle of Vaxsafe MS vaccine rapidly in a large (5 – 10 L) volume of warm (35-37°C) water. Mix the contents of the vial by gentle agitation during thawing. Invert the bottle repeatedly following thawing to ensure the contents have resuspended.
- Remove the central part of the crimp from the vaccine vials.
- Using a sterile syringe and needle, withdraw around 3mL of thawed Vaxsafe MS vaccine.
- Reconstitute the freeze-dried pellet of the MG304 vaccine by gently injecting the contents of the syringe through the vial stopper. The small vacuum in the vial will allow the contents of the diluent to be drawn into the vial.
- Gently swirl to mix the reconstituted freeze-dried pellet.
- Transfer the reconstituted vaccine into the thawed Vaxsafe MS bottle, ensuring that all vaccine is removed from the vial.
- Rinse the vial with a further 3 mL or more of reconstituted vaccine if necessary.
- Gently shake the reconstituted vaccine to mix the vaccine.
- Remove suspended vaccine from the Vaxsafe MS bottle and add the contents into a sterile container.
- Add 30 mL of sterile diluent from contents of the 30 mL dropper tip bottle.
- Gently shake the reconstituted vaccine to mix.
- Transfer the reconstituted vaccine (60 mL) into original 2 x 30 mL dropper tip bottles, ensuring that all vaccine is removed from the container.
- Fit the dropper tip to the dropper tip bottles to deliver 30 µL per drop.
- Use the entire contents within 4 hours after reconstitution.
- Hold each bird with its head tilted to one side.
- Deliver a single eye drop dose of ~30 microlitres (µL), using the dropper tip supplied with the vaccine, into the open eye gently flooding it. The drop (before release) should NOT touch the eye surface.
- Allow the bird to blink before releasing it.

WITHHOLDING PERIOD:

Meat: Zero days

Eggs: Zero days

USER SAFETY INFORMATION:

Additional information is available on the product Safety Data Sheet.

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.

In the event of self-administration, seek medical attention if you are concerned. Show the package leaflet or label to the medical practitioner.

FIRST AID:

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

STORAGE INSTRUCTIONS:

Vaxsafe MG304 should always be protected from direct sunlight. For long term storage, store below -18°C (deep freeze).

For short term storage (maximum of 6 months) of un-reconstituted Vaxsafe MG304, store between 2°C and 8°C (refrigerate, do not freeze).

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 in a designated and appropriately labelled biologicals container. 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.

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WARRANTY AND DISCLAIMER

Vaxsafe MG304 Vaccine (living) is supplied for use in chickens. 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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