

## FOR ANIMAL TREATMENT ONLY

# Vaxsafe<sup>®</sup> PM Vaccine (living)

**Active Constituent:** Each dose contains  $\geq 10^{7.2}$  cfu of live *Pasteurella multocida* strain PMP-1.

**Statement of Claims:** The vaccine is recommended as an aid in the control of fowl cholera due to infection with virulent homologous or heterologous strains of *Pasteurella multocida*.

This vaccine has been classified as a non-genetically modified organism by the Australian Office of the Gene Technology Regulator.

## 500, 1000 or 2000 Doses

**Contents:** The product consists of a freeze dried plug of vaccine within a 3 or 10 mL glass vial. Each vial contains 500, 1000 or 2000 doses.

Sterile diluent for vaccine preparation and administration is available separately in packs of 200 mL or 400 mL.

### READ DIRECTIONS CAREFULLY

#### DIRECTIONS FOR USE:

##### Contraindications

- This product is contraindicated for vaccinating unhealthy chickens.
- Do not administer to turkeys.

##### General directions

- The use of sterile equipment and proper sterile technique is critical to avoiding contamination of Vaxsafe<sup>®</sup> PM.
- 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.
- Time of administration: Early morning vaccination is recommended to allow minimum stress to the flock.

##### Precautions

- Exposure to disease must be minimised as much as possible especially during the first two weeks after vaccination.
- Avoid stressful conditions during and following vaccination.

##### Side effects

- Mild transient clinical signs such as inactivity or hunched posture may be noted in some birds following vaccination.
- This vaccine may cause swelling at the site of injection. This generally resolves within 28 days of the date of first vaccination and does not require specific treatment.

##### Dosage and Administration

Vaccine must be held between 4°C and 30°C prior to use.

Vaccine must be used within 4 hours of reconstitution. Discard unused vaccine after this period.

Reconstituted vaccine must not be frozen.

Administer 0.2 mL reconstituted vaccine by intramuscular injection to healthy birds over 8 weeks of age.

#### Vaccination Program

**Chickens:** Vaxsafe PM should be administered to growing birds from 8 to 14 weeks of age. A second vaccination with Vaxsafe<sup>®</sup> PM should be administered 4 weeks after the first vaccination. The optimum age of vaccination for each flock can be determined from records of previous outbreaks of fowl cholera on the farm. Requirement for further vaccinations will depend upon the severity of challenge on the farm.

Vaxsafe<sup>®</sup> PM has been shown to protect birds against fowl cholera caused by a virulent strain of *Pasteurella multocida* to at least 26 weeks after vaccination. Vaxsafe PM may be administered at the same time as combined inactivated NDV and EDS vaccines, and/or live Fowl Pox and AEV vaccines.

#### Method of Vaccination

##### Preparation of Vaccine for intramuscular injection

- Calculate the total number of vaccine doses required based on the total bird number rounded up to the nearest whole vial.
- Two 500 dose vials can be reconstituted using a single 200 mL pack of sterile diluent. If only a single 500 dose vial is to be reconstituted, using a syringe and needle accurately remove 100 mL of diluent prior to reconstitution and discard. This leaves 100 mL diluent in the pack for reconstitution of the vaccine.
- Each 1000 dose vial will require a 200 mL pack of sterile diluent. Each 2000 dose vial will require a 400 mL pack of sterile diluent.
- Use sterile needles, syringes and other equipment to avoid contamination of the product.
- The vaccine is supplied as a freeze-dried plug in a vial. This must be reconstituted before use.
- **For vaccine supplied in a 3 mL vial,** reconstitute the vaccine by removing 3 mL of vaccine diluent from the vaccine diluent pack using a sterile syringe and needle and injecting the diluent into the vial of vaccine.
- **For vaccine supplied in a 10 mL vial,** reconstitute the vaccine by removing 10 mL of vaccine diluent from the vaccine diluent pack using a sterile syringe and needle and injecting the diluent into the vial of vaccine.
- Gently shake through the vaccine vial bung, create a small vacuum and allow the contents of the vial to be drawn into the syringe.
- Remove all the resuspended vaccine from the vial with the syringe and inject the contents into the vaccine diluent bag.
- Ensure all vaccine is removed from the vial. For vaccine supplied in a 3 mL vial, rinse the vial with a further 3 mL of diluent if necessary. Alternatively, for vaccine supplied in a 10 mL vial, rinse the vial with a further 10 mL of diluent.
- Shake the diluent pack thoroughly but gently to mix the vaccine and the diluent.

##### Vaccination Procedure

Vaccine is administered to birds by intramuscular injection into either the left or right pectoral muscle. Ensure the injection is into the superficial pectoral muscle (not the deep pectoral muscle or inter-muscular sheath). The volume to be administered by intramuscular injection must be set at 0.2 mL.

#### WITHHOLDING PERIOD: Zero days

#### ADDITIONAL USER SAFETY INFORMATION:

Avoid contact with eyes.

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

Take care to avoid self-injection.

Additional information is available in the product Material Safety Data Sheet.

**FIRST AID:**

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

**STORAGE INSTRUCTIONS:**

Store below -18°C (deep freeze). Protect from light. The vaccine must be used prior to the expiry date marked on the label.

The sterile diluent is to be stored at room temperature.

**DISPOSAL:**

Discard unused diluent, 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® PM Vaccine (living) 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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