

# SALBUTAMOL GUAIFENESIN

## VENZADRIL™

1 mg/50 mg per 5 mL SYRUP

ANTIASTHMA/EXPECTORANT

### FORMULATION:

Each 5 mL (1 teaspoonful) contains:

Salbutamol (as sulfate) ..... 1 mg

Guaifenesin ..... 50 mg

### PRODUCT DESCRIPTION:

Salbutamol-Guaifenesin (Venzadril™) Syrup delivers the combined benefits of a bronchodilator, salbutamol, and a mucolytic, guaifenesin in the effective treatment of respiratory tract disorders associated with bronchospasm and excessive or thick, tenacious mucus secretions. Salbutamol and guaifenesin work in tandem to clear the airways. The two active ingredients relieve pulmonary obstruction caused by bronchospasm and abnormal or excessive bronchial secretions, thereby improving pulmonary ventilation.

### PHARMACODYNAMICS AND PHARMACOKINETICS:

Salbutamol is a direct acting sympathomimetic agent that acts selectively on beta-2 adrenergic receptors in the bronchial muscles. This results in bronchodilation thereby relieving bronchospasm. It has little or no action on cardiac receptors (beta-1 adrenergic receptors in the heart) so it produces much less cardiac stimulation. Salbutamol relaxes bronchial smooth muscles and expands or dilates the air passages to improve airflow.

Salbutamol also enhances mucociliary functions to help promote efficient mucus expectoration.

Guaifenesin promotes efficient expectoration of abnormal mucus secretions that accompany certain respiratory tract disorders. It is reported to reduce the viscosity of tenacious sputum.

Guaifenesin effectively loosens and dissolves excessive, viscid or thick mucus secretions present in the respiratory tract, thereby facilitating expectoration of bronchial mucus secretions that obstruct the respiratory air passages.

Following oral administration, salbutamol is well-absorbed from the gastrointestinal tract then metabolized in the liver. In the majority of patients, the effects of oral salbutamol usually last for 4-6 hours.

Salbutamol is excreted in the urine within 48-72 hours after oral administration, little is excreted via the feces.

Guaifenesin is well-absorbed from the gastrointestinal tract following oral administration. After metabolism, guaifenesin is excreted in the urine.

### INDICATIONS:

Used to increase the volume and reduce the viscosity of tenacious sputum and as an expectorant for productive cough; and as bronchodilator in the management of reversible airways obstruction, as in asthma and in some patients with chronic obstructive pulmonary disease.

### DOSAGE AND ADMINISTRATION:

Children:

2 - 6 yrs.: 5 - 10 mL (1 - 2 tsps.)

6 - 12 yrs.: 10 mL (2 tsps.)

Adults and children over 12 yrs.: 10 - 20 mL (2 - 4 tsps.)

To be taken 2 - 3 times a day, or as prescribed by the physician.

**CONTRAINDICATIONS/PRECAUTIONS/WARNINGS:**

Salbutamol-Guaifenesin (Venzadril™) should not be used in patients with history of hypersensitivity to salbutamol or guaifenesin.

Salbutamol should not be administered concomitantly with other sympathomimetic agents as it may cause adverse effects on the cardiovascular system.

Caution should be exercised in administering salbutamol to patients with thyroid disorders, myocardial insufficiency, arrhythmias, hypertension susceptibility to QT-interval prolongation and diabetes mellitus.

Salbutamol is contraindicated in patients who are taking non-selective beta-blocking agents like propranolol.

Salbutamol should be avoided during the first and second trimesters of pregnancy.

As the use of salbutamol with corticosteroids, diuretics or xanthines increases the risk of hypokalemia, monitoring of potassium concentrations is recommended in severe asthma.

Guaifenesin should be used with caution in patients who may develop persistent gastrointestinal upset due to intake of drug.

A physician must be consulted if cough persists for longer than 1 week and sore throat or fever is present with cough.

**PREGNANCY AND LACTATION:**

Pulmonary edema has been reported in pregnant women given with salbutamol for premature labor, although most cases are seen in patients given very high doses intravenously. Maternal effects include myocardial ischemia, unifocal ventricular ectopics and heart failure.

**ADVERSE DRUG REACTIONS:**

Salbutamol may cause fine tremors of the skeletal muscles specially the hands, nervous tension, headache, increased heart rate, palpitations, tachycardia, peripheral vasodilation and rarely muscle cramps in some patients. The said effects, which are common to all sympathomimetic drugs, are dose-related.

Potentially serious hypokalemia can occur in large doses. Hypersensitivity reactions including paradoxical bronchospasm, angioedema, urticaria, hypotension and collapse may also occur.

Adverse effects with guaifenesin are rare. Guaifenesin is safe and generally well tolerated. Nausea, vomiting and other mild gastrointestinal discomfort may occur in some individuals who are given very large doses.

**DRUG INTERACTIONS:**

Salbutamol should not be prescribed together with non-selective beta-adrenergic agents like propranolol. The use of salbutamol with corticosteroids, diuretics and xanthines may increase the risk of hypokalemia.

**OVERDOSE AND TREATMENT:**

Overdose with salbutamol includes tachycardia, CNS stimulation, tremors, hypokalemia, and hyperglycemia. Symptomatic management of these symptoms has proved to be valuable. In cases of oral overdose, activated charcoal may be considered.

**AVAILABILITY:**

Bottles of 60 mL

**CAUTION:**

Foods, Drugs, Devices and Cosmetics Act prohibits dispensing without prescription.

**STORE AT TEMPERATURES NOT EXCEEDING 30°C.**

DR-XY28890

For suspected adverse drug reactions, report to the FDA: [www.fda.gov.ph](http://www.fda.gov.ph)

# ***SVMore***

Manufactured for:

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