

SINA-12X[®]

Tablets

SINA-12X[®]

Suspension

IN-6301-06 Rev. 3/09

Description

SINA-12X[®] is a nasal decongestant/expectorant available for oral administration as a tablet and suspension.

Each tablet contains:

Phenylephrine Tannate 25 mg

Guaifenesin 200 mg

Other ingredients: dibasic calcium phosphate, FD&C Blue No. 1, FD&C Red No. 40, magnesium stearate, methylcellulose, polygalacturonic acid, povidone, silicon dioxide, starch, talc.

Each 5 mL (one teaspoonful) of the purple-colored, grape flavored suspension contains:

Phenylephrine Tannate 5 mg

Guaifenesin 100 mg

Other ingredients: benzoic acid, FD&C Blue No. 1, FD&C Red No. 3, FD&C Red No. 40, flavors (natural and artificial), glycerin, kaolin, magnesium aluminum silicate, methylparaben, pectin, purified water, saccharin sodium, sodium hydroxide, sucrose.

Clinical Pharmacology

Phenylephrine is a sympathomimetic nasal decongestant which acts predominantly on alpha adrenergic receptors in the mucosa of the respiratory tract, producing vasoconstriction with minimal action on beta receptors. It functions as an oral nasal decongestant with minimal central nervous system (CNS) stimulation and it promotes sinus drainage. Guaifenesin is an expectorant which increases the output of phlegm (sputum) and bronchial secretions by reducing adhesiveness and surface tension. The increased flow of less viscid secretions promotes ciliary action and changes a dry, unproductive cough to one that is more productive and less frequent.

Indications and Usage

For the temporary relief of nasal congestion and dry nonproductive cough associated with the common cold, sinusitis, and other respiratory allergies. Helps drainage of the bronchial tubes by thinning the mucus.

Contraindications

This product is contraindicated in patients with known hypersensitivity to any of its ingredients. Also contraindicated in patients with severe hypertension, severe coronary artery disease and patients on monoamine oxidase (MAO) inhibitor therapy.

Warnings

This product should be prescribed with caution in patients with persistent or chronic cough such as occurs with smoking, asthma, or emphysema, or where cough is accompanied by excessive secretions. Advise patients to take medication a few hours before bedtime to minimize the possibility of sleeplessness. The medication should be taken with a glass of water after each dose, to help loosen mucus in the lungs. Use with caution in patients with hypertension, cardiovascular disease, hyperthyroidism, diabetes mellitus, narrow angle glaucoma or prostatic hypertrophy.

Precautions

Information for patients: Patients should be warned not to use this product if they are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If patients are uncertain whether a prescription drug contains an MAOI, they should be instructed to consult a health professional before taking such a product.

Drug interactions: MAO inhibitors may prolong and intensify the overall effects of sympathomimetic agents.

Carcinogenesis, mutagenesis, impairment of fertility: No long-term animal studies have been performed with this product.

Pregnancy: Teratogenic effects: Pregnancy Category C. Animal reproductive studies have not been conducted with this product. It is also not known whether this product can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. This product should be given to a pregnant woman only if clearly needed.

Nursing mothers: This product should not be administered to a nursing woman.

Geriatrics: Phenylephrine should be used with caution in the elderly because they may be more sensitive to the effects of sympathomimetics.

Laboratory test interactions: Guaifenesin or its metabolites may cause color interference with the VMA (vanillylmandelic acid) test for catechols. It may also falsely elevate the level of urinary 5-HIAA (5-hydroxyindoleacetic acid) in certain serotonin metabolite chemical tests because of color interference.

Adverse Reactions

To report SUSPECTED ADVERSE REACTIONS, contact Meda Pharmaceuticals Inc. at 1-800-526-3840 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Adverse reactions associated with phenylephrine may include nervousness, restlessness and headache. Serious side effects with sympathomimetics have been rare. Guaifenesin is well tolerated and has a wide margin of safety. Side effects have been generally mild and infrequent. Nausea and vomiting are the side effects that occur most commonly. Dizziness, headache, and rash (including urticaria) have been reported rarely.

Overdosage

Signs & symptoms: CNS stimulation (restlessness to convulsions).

Treatment: Induce vomiting if it has not occurred spontaneously. Precautions must be taken against aspiration especially in infants, children and comatose patients. If gastric lavage is indicated, isotonic or half-isotonic saline solution is preferred. Stimulants should not be used. Treatment is symptomatic and supportive. The acute toxicity of guaifenesin is low and overdosage is unlikely to produce serious toxic effects. In laboratory animals, no toxicity resulted when guaifenesin was administered by stomach tube in doses up to 5 grams/kg.

Dosage and Administration

Administer the recommended dose every 12 hours.

SINA-12X[®] Tablets: *Adults and children 12 years of age and older* — 1 or 2 tablets. *Children 6 to 11 years* — 1/2 or 1 tablet.

SINA-12X[®] Suspension: *Children over six years of age* — 5 to 10 mL (1 to 2 teaspoonfuls); *Children two to six years of age* — 2.5 to 5 mL (1/2 to 1 teaspoonful); *Children under two years of age* — Titrate dose individually.

How Supplied

SINA-12X[®] Tablets (phenylephrine tannate 25 mg, guaifenesin 200 mg): purple-colored, capsule-shaped, scored on one side and imprinted SINA 6301 on the other side. The tablets are available in bottles of 30 (NDC 0037-6301-03).

Storage: Store at controlled room temperature 20°-25°C (68°-77°F). Protect from moisture. Dispense in a tight container.

SINA-12X[®] Suspension (phenylephrine tannate 5 mg, and guaifenesin 100 mg per 5 mL) is purple with grape flavor. The suspension is available in a 4 fl oz unit of use container with a 10 mL graduated oral syringe and fitment (NDC 0037-6302-04).
Storage: Store at controlled room temperature 20°-25°C (68°-77°F).

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