TANAFED DMX™ SUSPENSION

Rx Only

DESCRIPTION:
Each 5 mL contains:

Dexchlorpheniramine tannate	2.5 mg
Pseudoephedrine tannate	75.0 mg
Dextromethorphan tannate	25.0 mg

in a blue, cotton candy flavored, homogeneous suspension.
Inactive ingredients: citric acid, FD&C Blue #1, flavor, glycerin, magnesium aluminum silicate, methylparaben, sodium benzoate, sodium citrate, sodium saccharin, sucrose, purified water, xanthan gum.

CLINICAL PHARMACOLOGY:
Dexchlorpheniramine tannate antagonizes the physiological action of histamine by acting as an H_1 receptor blocking agent. *In vitro* and *in vivo* assays of the antihistamine potencies of the optically active isomers of chlorpheniramine demonstrate that the predominant activity is in the dextro-isomer. The dextro-isomer is approximately two times more active than the racemic compound. *Pseudoephedrine tannate* is an orally active sympathomimetic amine and exerts a decongestant action on the nasal mucosa. It does this by vasoconstriction, which results in reduction of tissue hyperemia, edema, nasal congestion and an increase in nasal airway patency. The vasoconstrictive action of pseudoephedrine is similar to that of ephedrine. In the usual dose it has minimal vasopressor effects. The cough suppressant action of *Dextromethorphan tannate* is due to a central action on the cough center in the medulla. It has no analgesic or addictive properties.

INDICATIONS:
Temporarily relieves nasal congestion and pressure, runny nose, sneezing, itching of the nose or throat, itchy, watery eyes, and cough due to minor throat and bronchial irritation associated with the common cold, sinusitis, hay fever, or other upper respiratory allergies (allergic rhinitis).

CONTRAINDICATIONS:
Hypersensitivity to any of the ingredients. Do not use in patients receiving MAO inhibitors (See **PRECAUTIONS: Drug Interactions**). Antihistamines should not be used to treat lower respiratory tract conditions including asthma.

WARNINGS:
Do not exceed recommended dosage. If nervousness, dizziness, or sleeplessness occur, discontinue use and consult a physician. If symptoms do not improve within 7 days or are accompanied by fever, consult a physician. Do not take this product if you have heart disease, high blood pressure, thyroid disease, diabetes or difficulty in urination due to enlargement of the prostate gland unless directed by a physician. Dexchlorpheniramine tannate should be used with extreme caution in patients with stenosing peptic ulcer, pyloroduodenal obstruction, or bladder neck obstruction. Due to its mild atropine-like action, dexchlorpheniramine tannate should be used cautiously in patients with bronchial asthma. Do not take this product, unless directed by a physician, if you have a breathing problem such as emphysema or chronic bronchitis, or if you have glaucoma. Especially in infants and small children, antihistamines in overdosage may cause hallucinations, convulsions, and death. Antihistamines may diminish mental alertness. In young children they may produce excitation. Dextromethorphan may be accompanied by histamine release and should be used with caution in atopic children. A persistent cough may be a sign of a serious condition. If cough persists for more than one week, tends to recur or is accompanied by fever, rash, or persistent headache, consult a physician. Do not take this product for persistent or chronic cough such as occurs with smoking, asthma, emphysema, or if cough is accompanied by excessive phlegm (mucus) unless directed by a physician.

PRECAUTIONS:
Information for patients
May cause drowsiness; alcohol, sedatives, and tranquilizers may increase the drowsiness affect. Avoid alcoholic beverages while taking this product. Do not take this product if you are taking sedatives or tranquilizers, without first consulting your physician. Use caution when driving a motor vehicle or operating machinery.

Drug Interactions
Do not use in patients receiving 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 you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product. The use of dextromethorphan may result in additive CNS depressant effects when coadministered with alcohol, antihistamines, psychotropics or other drugs that produce CNS depression. Patients may develop hypotension, hyperpyrexia, nausea, myoclonic leg jerks and coma following coadministration of MAO inhibitors and dextromethorphan. MAO inhibitors also prolong and intensify the anticholinergic effects of antihistamines. Sympathomimetics may reduce the antihypertensive effect of methyldopa, reserpine, veratrum alkaloids and mecamylamine. Alcohol and other sedative drugs will potentiate the sedative effects of dexchlorpheniramine. Care should be taken in administering this product concomitantly with other

sympathomimetic amines since their combined effects on the cardiovascular system may be harmful to the patient.

Carcinogenesis, Mutagenesis, Impairment of Fertility
No long-term animal studies have been performed with Tanafed DMX™ Suspension.

Pregnancy
Pregnancy Category C: Animal reproduction studies have not been conducted with this product. It is not known whether this medication 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: Due to the possible passage of pseudoephedrine, dextromethorphan, and dexchlorpheniramine into breast milk, and, because of the higher than usual risk for infants from sympathomimetic amines and antihistamines, the benefit to the mother vs. the potential risk should be considered and a decision should be made whether to discontinue nursing or to discontinue the drug.

ADVERSE REACTIONS:

Dexchlorpheniramine Tannate

Slight to moderate drowsiness may occur and is the most frequent side effect. Other possible side effects of antihistamines in general include:
General: urticaria, drug rash, anaphylactic shock, photosensitivity, excessive perspiration, chills, dryness of mouth, nose and throat;
Cardiovascular: hypotension, headache, palpitation, tachycardia, extrasystoles;
Hematologic: hemolytic anemia, thrombocytopenia, agranulocytosis;
CNS: sedation, dizziness, disturbed coordination, fatigue, confusion, restlessness, excitation, nervousness, tremor, irritability, insomnia, euphoria, paresthesia, blurred vision, diplopia, vertigo, tinnitus, hysteria, neuritis, convulsion;
Gastrointestinal: epigastric distress, anorexia, nausea, vomiting, diarrhea, constipation;
Genitourinary: urinary frequency, difficult urination, urinary retention, early menses;
Respiratory: thickening of bronchial secretions, tightness of chest, wheezing and nasal stuffiness.

Dextromethorphan Tannate

Rare drowsiness or mild gastrointestinal disturbances are the only side effects associated with dextromethorphan in clinical use. (See also Drug Interactions)

Pseudoephedrine Tannate

Pseudoephedrine may cause mild central nervous system stimulation, especially in those patients who are hypersensitive to sympathomimetic drugs. Nervousness, excitability, restlessness, dizziness, weakness and insomnia may also occur. Headache and drowsiness have also been reported. Large doses may cause lightheadedness, nausea and/or vomiting. Sympathomimetic drugs have also been associated with certain untoward reactions including fear, anxiety, tenseness, restlessness, tremor, weakness, pallor, respiratory difficulty, dysuria, insomnia, hallucination, convulsion, CNS depression, arrhythmias and cardiovascular collapse with hypotension.

OVERDOSAGE:
Signs & Symptoms - May vary from CNS depression to stimulation (restlessness to convulsions). Antihistamine overdosage in young children may lead to convulsions and death. Atropine-like signs and symptoms may be prominent.

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. If hypotension is a problem, vasopressor agents may be considered.

DOSAGE AND ADMINISTRATION:
Administer the recommended dose every 12 hours.

Adults and children over 12 years- 10 to 20 mL (2 to 4 teaspoonsful) not to exceed 8 teaspoonsful in 24 hours.
Children 6 to 12 years- 5 to 10 mL (1 to 2 teaspoonsful) not to exceed 4 teaspoonsful in 24 hours.
Children 2 to 6 years- 2.5 to 5 mL (1/2 to 1 teaspoonful) not to exceed 2 teaspoonsful in 24 hours.
Children under 2 years – Consult a physician.

NOTE: The tannate salts of pseudoephedrine, dexchlorpheniramine, and dextromethorphan have much higher molecular weights than the corresponding salts of the active base compounds; therefore, even though the dosage (by milligram weight) of the tannate salt may seem high, the proportion of pseudoephedrine, dexchlorpheniramine, and dextromethorphan in the tannate salts approach those in the corresponding hydrochloride, maleate, and hydrobromide salts. The percentage of pseudoephedrine in pseudoephedrine tannate is approximately 29% while in pseudoephedrine hydrochloride the pseudoephedrine is approximately 82%. Similarly, the percentage of dexchlorpheniramine in dexchlorpheniramine tannate is approximately 45% while the dexchlorpheniramine percentage in dexchlorpheniramine maleate is approximately 70%. Also, the percentage of dextromethorphan in dextromethorphan tannate is approximately 42% while the dextromethorphan percentage in dextromethorphan hydrobromide is approximately 77%.

HOW SUPPLIED:
Tanafed DMX™ Suspension, each teaspoonful (5mL) of which contains dexchlorpheniramine tannate 2.5 mg; dextromethorphan tannate 25.0 mg; and pseudoephedrine tannate 75.0 mg is supplied as a blue colored, cotton candy flavored homogeneous suspension. Tanafed DMX™ Suspension is available in bottles of 16 fl oz (473 mL) NDC 59630-470-16; in bottles of 4 fl oz (118 mL) NDC 59630-470-04; and in bottles of 20 mL NDC 59630-470-20.

Dispense in a tight, light-resistant container with a child-resistant closure. Shake well before use.

Store at controlled room temperature 15° - 30° C (59°- 86° F). Protect from freezing.

Keep this and all drugs out of the reach of children. In case of accidental overdose, seek professional assistance or contact a Poison Control Center immediately.

Manufactured by:
ELGE, INC.
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Manufactured for:
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U.S. Patent 5,663,415;
Other patents pending

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