

TUSSI-12 D®
Tablets
TUSSI-12 D® S
Suspension

IN-0692-05 Rev. 3/09

Description

TUSSI-12D is an antitussive/antihistamine/nasal decongestant combination available for oral administration as Tablets and as a Suspension.

Each tablet contains:

Carbetapentane Tannate	60 mg
Pyrimilamine Tannate	40 mg
Phenylephrine Tannate	10 mg

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

Each 5 mL (one teaspoonful) of the suspension contains:

Carbetapentane Tannate	30 mg
Pyrimilamine Tannate	30 mg
Phenylephrine Tannate	5 mg

Other ingredients: benzoic acid, FD&C Blue No. 1, FD&C Red No. 3, FD&C Red No. 40, FD&C Yellow No. 5 (see Precautions), flavors (natural and artificial), glycerin, kaolin, magnesium aluminum silicate, methylparaben, pectin, purified water, saccharin sodium, sucrose.

Clinical Pharmacology

TUSSI-12D Tablets and TUSSI-12D S Suspension combine the antitussive action of carbetapentane, the sympathomimetic decongestant effect of phenylephrine, and the antihistaminic action of pyrimilamine.

Indications and Usage

TUSSI-12D Tablets and TUSSI-12D S Suspension are indicated for the symptomatic relief of cough associated with respiratory tract conditions such as the common cold, bronchial asthma, acute and chronic bronchitis. Appropriate therapy should be provided for the primary disease.

Contraindications

TUSSI-12D Tablets and TUSSI-12D S Suspension are contraindicated for newborns, nursing mothers, and patients who are sensitive to any of the ingredients or related compounds.

Warnings

Use with caution in patients with hypertension, cardiovascular disease, hyperthyroidism, diabetes, narrow angle glaucoma, or prostatic hypertrophy. Do not use in patients taking monoamine oxidase (MAO) inhibitors, or for 14 days after stopping treatment with an MAOI.

This product contains an antihistamine which may cause drowsiness and may have additive central nervous system (CNS) effects with alcohol or other CNS depressants (e.g., hypnotics, sedatives, tranquilizers).

Precautions

TUSSI-12D S Suspension contains FD&C Yellow No. 5 (tartrazine) which may cause allergic-type reactions (including bronchial asthma) in certain susceptible individuals. Although the overall incidence of FD&C Yellow No. 5 (tartrazine) sensitivity in the general population is low, it is frequently seen in patients who also have aspirin hypersensitivity.

General: Antihistamines are more likely to cause dizziness, sedation, and hypotension in elderly patients. Antihistamines may cause excitation, particularly in children, but their combination with sympathomimetics may cause either mild stimulation or mild sedation.

Information for patients: Caution patients against drinking alcoholic beverages or engaging in potentially hazardous activities requiring alertness, such as driving a car or operating machinery, while using this product. 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 anticholinergic effects of antihistamines and sympathomimetics.

Carcinogenesis, mutagenesis, impairment of fertility: No long term animal studies have been performed with TUSSI-12D Tablets or TUSSI-12D S Suspension.

Pregnancy: Teratogenic effects: Pregnancy Category C. Animal reproduction studies have not been conducted with TUSSI-12D Tablets or TUSSI-12D S Suspension. It is also not known whether TUSSI-12D Tablets or TUSSI-12D S Suspension can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. TUSSI-12D Tablets or TUSSI-12D S Suspension should be given to a pregnant woman only if clearly needed.

Nursing mothers: TUSSI-12D Tablets or TUSSI-12D S Suspension should not be administered to a nursing woman.

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 may include drowsiness, sedation, dryness of mucous membranes, and gastrointestinal effects. Serious side effects with oral antihistamines or sympathomimetics have been rare.

Overdosage

Signs and 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.

TUSSI-12D Tablets: Adults and children 12 years and older — 1 to 2 tablets.

Children 6 to 11 years — 1/2 or 1 tablet.

TUSSI-12D S Suspension: *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

TUSSI-12D Tablets are pink-colored, capsule-shaped, scored on one side and imprinted WALLACE 0692 on the other side, containing in each tablet: carbetapentane tannate 60 mg, pyrimilamine tannate 40 mg, phenylephrine tannate 10 mg, available in bottles of 100 (NDC 0037-0692-10).

TUSSI-12D S Suspension is pink with strawberry-currant flavor, containing in each 5 mL (one teaspoonful): carbetapentane tannate 30 mg, pyrimilamine tannate 30 mg, phenylephrine tannate 5 mg, available in 4 fl oz unit of use containers with a 10 mL graduated oral syringe and fitment (NDC 0037-0693-04).

Storage: Store at controlled room temperature 20°-25°C (68°-77°F).

Dispense in a tight container.

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