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## Tavist D advertisement.

[s.l.]: [s.n.], 1986

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Because your patient is the  
**ULTIMATE  
PROVING GROUND**



# A PROVEN COMBINATION\*

antihistamine/decongestant

## TAVIST<sup>D</sup>

TABLETS

*(clemastine fumarate 1.34 mg, phenylpropanolamine HCl 75 mg extended-release tablets)*

**Effective** relief is why physicians and patients rely on Tavist-D. Time after time, in patient after patient, Tavist-D provides effective symptom relief of allergic rhinitis and nasal congestion. Plus, Tavist-D provides your patients with 12-hour relief for symptom-free days and restful nights.

**Experience**—Physicians have made Tavist-D the #1 prescribed antihistamine/decongestant tablet for 4 consecutive years.\* Over 16 million prescriptions have been written; this has demonstrated proven efficacy that you and your patients can count on.

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A proven combination  
works all day...all night



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# TAVIST D<sup>®</sup>

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### BRIEF SUMMARY

#### TAVIST-D<sup>®</sup>

(clemastine fumarate, phenylpropanolamine HCl, extended-release tablets) Each tablet contains: clemastine fumarate, 1.34 mg, phenylpropanolamine HCl, 75 mg.

### INDICATIONS AND USAGE

Tavist-D<sup>®</sup> (clemastine fumarate/phenylpropanolamine HCl) Tablets are indicated for the relief of symptoms associated with allergic rhinitis such as sneezing, rhinorrhea, pruritus of the eyes, nose or throat, lacrimation and nasal congestion.

### CONTRAINDICATIONS

Tavist-D<sup>®</sup> (clemastine fumarate/phenylpropanolamine HCl) Tablets are contraindicated in patients hypersensitive to any of the components. Antihistamines should not be used in newborn or premature infants or in nursing mothers. Antihistamines should not be used to treat lower respiratory tract symptoms including asthma. Tavist-D<sup>®</sup> (clemastine fumarate/phenylpropanolamine HCl) Tablets are contraindicated in patients receiving monoamine oxidase inhibitors (see **PRECAUTIONS — Drug Interactions** in a complete package insert) and in patients with severe hypertension or severe coronary artery disease.

### WARNINGS

Antihistamines such as clemastine fumarate should be used with considerable caution in patients with narrow angle glaucoma, stenosing peptic ulcer, pyloroduodenal obstruction, symptomatic prostatic hypertrophy, and bladder neck obstruction. Sympathomimetic drugs such as phenylpropanolamine hydrochloride should be used with caution in hypertension, cardiovascular disease, diabetes mellitus, and uncontrolled hyperthyroidism.

**Use with CNS Depressants:** Antihistamines have additive effects with alcohol and other CNS depressants (hypnotics, sedatives, tranquilizers, etc.).

**Use in Activities Requiring Mental Alertness:** Patients should be warned about engaging in activities requiring mental alertness such as driving a car or operating appliances, machinery, etc.

**Use in the Elderly (approximately 60 years or older):** Antihistamines are more likely to cause dizziness, sedation and hypotension in elderly patients. Overdosages of sympathomimetics in this age group may cause hallucinations, convulsions, CNS depression and death in elderly patients.

**Use in Children:** Safety and effectiveness of Tavist-D<sup>®</sup> (clemastine fumarate/phenylpropanolamine HCl) have not been established in children under the age of 12. In infants and children, especially, antihistamines in *overdosage* may cause hallucinations, convulsions or death. As in adults, antihistamines may diminish mental alertness, but they may also produce excitation, particularly in young children.

### ADVERSE REACTIONS

**Antihistaminic Compounds:** It should be noted that the following reactions have occurred with one or more antihistamines and, therefore, should be kept in mind when prescribing drugs belonging to this class, including clemastine fumarate. The most frequent adverse reactions reported with clemastine fumarate are underlined.

1. **General:** Urticaria, drug rash, anaphylactic shock, photosensitivity, excessive perspiration, chills, dryness of mouth, nose and throat.
2. **Cardiovascular System:** Hypotension, headache, palpitations, tachycardia, extrasystoles.
3. **Hematologic System:** Hemolytic anemia, thrombocytopenia, agranulocytosis.
4. **Nervous System:** Sedation, sleepiness, dizziness, disturbed coordination, fatigue, confusion, restlessness, excitation, nervousness, tremor, irritability, insomnia, euphoria, paresthesias, blurred vision, diplopia, vertigo, tinnitus, acute labyrinthitis, hysteria, neuritis, convulsions.
5. **Gastrointestinal System:** Epigastric distress, anorexia, nausea, vomiting, diarrhea, constipation.
6. **Genitourinary System:** Urinary frequency, difficult urination, urinary retention, early menses.
7. **Respiratory System:** Thickening of bronchial secretions, tightness of chest and wheezing, nasal stuffiness.

**Sympathomimetic Compounds:** **Nervous System** — At higher doses may cause drowsiness, dizziness, nervousness, or sleeplessness, and especially in children may cause excitability. Phenylpropanolamine hydrochloride may cause elevated blood pressure and tachyarrhythmias, especially in hyperthyroid patients.

### DOSAGE AND ADMINISTRATION

Adults and children twelve years and over: One tablet swallowed whole every twelve hours.

### HOW SUPPLIED

Tavist-D<sup>®</sup> (clemastine fumarate/phenylpropanolamine HCl, extended-release) Tablets: Containing 1.34 mg clemastine fumarate (equivalent to 1 mg of the free base) and 75 mg phenylpropanolamine hydrochloride. White, round film-coated multiple compressed tablet, embossed "TAVIST-D" on one side and "78-221" on the other. Packages of 100 (NDC 0078-0221-05).

TAD-0190-01

\*Standard industry prescription audits. Data on file, Sandoz Pharmaceuticals Corporation.



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