Brief Summary Tavist[®] (clemastine fumarate) tablets, USP 2.68 mg

INDICATIONS: TAVIST Tablets 2.68 mg are indicated for the relief of symptoms associated with allergic rhinitis such as sneezing, rhinorrhea, pruritus, and lacrimation. TAVIST Tablets 2.68 mg are also indicated for the relief of mild, uncomplicated allergic skin manifestations of urticaria and angioedema.

CONTRAINDICATIONS: Use in Nursing Mothers: Because of the higher risk of antihistamines for infants generally and for newborns and prematures in particular, antihistamine therapy is contraindicated in nursing mothers.

Use in Lower Respiratory Disease: Antihistamines should not be used to treat lower respiratory tract symptoms including asthma. Antihistamines are also contraindicated in the following conditions:

Hypersensitivity to TAVIST (clemastine fumarate) or other antihistamines of similar chemical structure.

Monoamine oxidase inhibitor therapy (see Drug Interaction Section).

WARNINGS: Antihistamines should be used with considerable caution in patients with: narrow angle glaucoma, stenosing peptic ulcer, pyloroduodenal obstruction, symptomatic prostatic hypertrophy, and bladder neck obstruction.

Use in Children: Safety and efficacy of TAVIST have not been established in children under the age of 12.

Use in Pregnancy: Experience with this drug in pregnant women is inadequate to determine whether there exists a potential for harm to the developing fetus.

Use with CNS Depressants: TAVIST has 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.

PRECAUTIONS: TAVIST (clemastine fumarate) should be used with caution in patients with: history of bronchial asthma, increased intracoular pressure, hyperthyroidism, cardiovascular disease, and hypertension.

Drug Interactions: MAO inhibitors prolong and intensify the anticholinergic (drying) effects of antihistamines.

ADVERSE REACTIONS: Transient drowsiness, the most common adverse reaction associated with TAVIST (clemastine fumarate), occurs relatively frequently and may require discontinuation of therapy in some instances.

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 TAVIST. The most frequent adverse reactions are underlined.

- 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.
- Nervous System: Sedation, sleepiness, dizziness, disturbed coordination, latigue, confusion, restlessness, excitation, nervousness, tremor, irritability, insomnia, euphoria, paresthesias, blurred vision, diplopia, vertigo, tinnitus, acute labyrinthitis, hysteria, neuritis, convulsions.
- GI System: Epigastric distress, anorexia, nausea, vomiting, diarrhea, constipation.
- 6. GU System: Urinary frequency, difficult urination, urinary retention, early menses.
- Respiratory System: Thickening of bronchial secretions, tightness of chest and wheezing, nasal stuffiness.

DOSAGE AND ADMINISTRATION: DOSAGE SHOULD BE IN-DIVIDUALIZED ACCORDING TO THE NEEDS AND RESPONSE OF THE PATIENT.

TAVIST Tablets 2.68 mg: The maximum recommended dosage is one tablet three times daily. Many patients respond favorably to a single dose which may be repeated as required, but not to exceed three tablets daily.

HOW SUPPLIED: TAVIST Tablets: 2.68 mg clemastine fumarate. White, round compressed tablet, embossed "78/72" and scored on one side, "TAVIST" on the other. Packages of 100.

CAUTION: Federal law prohibits dispensing without prescription.

TAV-Z2(A)

10/1/85



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LETTERS TO THE EDITOR

The Journal welcomes Letters to the Editor; if found suitable, they will be published as space allows. Letters should be typed double-spaced, should not exceed 400 words, and are subject to abridgment and other editorial changes in accordance with journal style.

HYPNOTHERAPY AND SMOKING CESSATION

To the Editor:

I appreciated the work that went into the controlled study "Hypnotherapy for Smoking Cessation,' which appeared in the January 1986 issue of The Journal (Lambe R, Osier C, Franks P: A randomized controlled trial of hypnotherapy for smoking cessation. J Fam Pract 1986; 22:61-65). Although it seemed at some level to be a thorough study of this subject, some of the most critical variables were not considered. A study on this subject that does not monitor these variables calls into question any conclusions the study made on the effectiveness of hypnotherapy and self-hypnosis.

1. I do not believe that hypnotherapy and self-hypnosis have any magical cure to offer people who want to stop smoking even though I believe it is a very powerful technique. In my opinion, there are no techniques to help a person stop smoking unless she or he has made a firm commitment to quit. In a study on this subject, level of commitment must be addressed even though it is difficult to measure.

2. The second variable that must be addressed is an assessment of the reason or reasons behind the smoking habit. In a study on this subject, the group to be evaluated must be composed of people who believe that smoking is the problem and not the symptom of a problem. For instance, if a person smokes because of stress or nervousness or anxiety, then any attempt to stop smoking will probably be unsuccessful.

3. The third variable, which was mentioned briefly in the article, is the level of trance and the daily practice of self-hypnosis. To determine the effectiveness of hypnotherapy and self-hypnosis, the subject should be taught to induce a medium level trance and then be required to practice a self-hypnotic exercise for 20 minutes two times a day for three to six months depending on the time frame of the study. If the subject is successfully taught self-hypnosis and does not use it daily in the prescribed fashion, then the failure to stop smoking says much more about the person than it does about the effectiveness of hypnotherapy and self-hypnosis.

Because these three variables were not adequately addressed, I do not believe the conclusions of the study can be given much credibility. Hypnotherapy and selfhypnosis are very powerful techniques, but self-hypnosis must be practiced daily to be effective. As one wise person said, "Health and wholeness come to those who are willing to chop wood and carry water."

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