Although trihexyphenidyl HCl is not contraindicated for patients with:

**WARNINGS**

- Patients to be treated with trihexyphenidyl HCl should have a central nervous system reaction to commonly employed tranquilizers, notably the phenothiazines, thioxanthenes, and butyrophenones.

- Trihexyphenidyl HCl may be better to take it before meals, unless it causes nausea. If taken after meals, the thirst sometimes induced can be alleviated by mint candies, chewing gum or water.

**INDICATIONS AND USAGE**

Trihexyphenidyl HCl tablets are indicated as an adjunct in the treatment of all forms of parkinsonism (postencephalitic, arteriosclerotic, and idiopathic). It is often useful as adjuvant therapy when treating these forms of parkinsonism with levodopa. Additionally, it is indicated for the control of extrapyramidal disorders caused by drugs of this type, and hence, require strict dosage regulation.

**PRECAUTIONS**

Although trihexyphenidyl HCl is not contraindicated for patients with cardiac, liver, or kidney disorders, or with hypertension, such patients should be maintained under close observation. Since the use of trihexyphenidyl HCl may, in some cases, continue indefinitely and since it has atropine-like properties, patients should be subjected to constant and careful long-term observation to avoid allergic and other untoward reactions. Inasmuch as trihexyphenidyl HCl possesses some parasympatholytic activity, it should be used with caution in patients with glaucoma, obstructive disease of the gastrointestinal or genitourinary tracts, and in elderly males with possible prostatic hypertrophy. Geriatric patients, particularly over the age of 60, frequently develop increased sensitivity to the actions of drugs of this type, and hence, require strict dosage regulation. Incipient glaucoma may be precipitated by parasympatholytic drugs such as trihexyphenidyl HCl.

**ADVERSE REACTIONS**

Minor side effects, such as dryness of the mouth, blurring of vision, dizziness, mild nausea or nervousness, will be experienced by 30 to 50 percent of all patients. These sensations, however, are much less disturbing than unalleviated parkinsonism.

**HOW SUPPLIED**

Trihexyphenidyl HCl tablets are available as follows:
- **Rx only**

**CONTRAINDICATIONS**

Trihexyphenidyl HCl is contraindicated for patients with glaucoma, narrow-angle glaucoma, or with a history of idiosyncrasy to other drugs that may exhibit reactions of mental confusion, agitation, disturbed behavior, or nausea and vomiting. Such patients should be allowed to develop a tolerance through the initial administration of a small dose and gradual increase in dose until an effective level is reached. If a severe reaction should occur, administration of the drug should be discontinued for a few days and then resumed at a lower dosage. Psychiatric disturbances can result from indiscriminate use (leading to overdosage) to sustain continued euphoria.

**DOSEAGE AND ADMINISTRATION**

Dosage should be individualized. The initial dose should be low and then increased gradually, especially in patients over 60 years of age. Whether trihexyphenidyl HCl may best be given before or after meals should be determined by the way the patient reacts. Postencephalitic patients, who are usually more prone to excessive salivation, may prefer to take it after meals and may, in addition, require small amounts of atropine which, under such circumstances, is sometimes an effective adjuvant. If trihexyphenidyl HCl tends to dry the mouth excessively, it may be better to take it before meals, unless it causes nausea. If taken after meals, the thirst sometimes induced can be alleviated by mint candies, chewing gum or water.

**RX only**

**TRIHEXYPHENIDYL HYDROCHLORIDE TABLETS, USP**

**DESCRIPTION**

Trihexyphenidyl HCl is a synthetic antispasmodic. Each tablet for oral administration contains 2 mg or 5 mg trihexyphenidyl HCl, each strength also containing as inactive ingredients: magnesium stearate, microcrystalline cellulose, and sodium starch glycolate. Trihexyphenidyl HCl is a white or slightly off white, crystalline powder, having not more than a very faint odor.

**CLINICAL PHARMACOLOGY**

Trihexyphenidyl HCl tablets are direct action anticholinergics, exerted both directly upon the muscle tissue itself and indirectly through an inhibitory effect upon the parasympathetic nervous system. Its therapeutic properties are similar to those of atropine, although undesirable side effects are ordinarily less frequent and severe than with the latter.

**INDICATIONS AND USAGE**

Trihexyphenidyl HCl tablets are indicated as an adjunct in the treatment of all forms of parkinsonism (postencephalitic, arteriosclerotic, and idiopathic). It is often useful as adjuvant therapy when treating these forms of parkinsonism with levodopa. Additionally, it is indicated for the control of extrapyramidal disorders caused by central nervous system drugs such as the dibenzoxazepines, phenothiazines, thioxanthenes, and butyrophenones.

**WARNINGS**

Patients to be treated with trihexyphenidyl HCl should have a gonioscope evaluation and close monitoring of intraocular pressures at regular periodic intervals.

**PRECAUTIONS**

Although trihexyphenidyl HCl is not contraindicated for patients with cardiac, liver, or kidney disorders, or with hypertension, such patients should be maintained under close observation.

Since the use of trihexyphenidyl HCl may, in some cases, continue indefinitely and since it has atropine-like properties, patients should be subjected to constant and careful long-term observation to avoid allergic and other untoward reactions. Inasmuch as trihexyphenidyl HCl possesses some parasympatholytic activity, it should be used with caution in patients with glaucoma, obstructive disease of the gastrointestinal or genitourinary tracts, and in elderly males with possible prostatic hypertrophy. Geriatric patients, particularly over the age of 60, frequently develop increased sensitivity to the actions of drugs of this type, and hence, require strict dosage regulation. Incipient glaucoma may be precipitated by parasympatholytic drugs such as trihexyphenidyl HCl.

Tardive dyskinesia may appear in some patients on long-term therapy with antipsychotic drugs or may occur after therapy with these drugs has been discontinued. Antiparkinsonism agents do not alleviate the symptoms of tardive dyskinesia and, in some instances, may aggravate them. However, parkinsonism and tardive dyskinesia often coexist in patients receiving chronic neuroleptic treatment, and anticholinergic therapy with trihexyphenidyl HCl may relieve some of these parkinsonism symptoms.

**ADVERSE REACTIONS**

Minor side effects, such as dryness of the mouth, blurring of vision, dizziness, mild nausea or nervousness, will be experienced by 30 to 50 percent of all patients. These sensations, however, are much less disturbing than unalleviated parkinsonism. Such reactions tend to become less pronounced, and even to disappear, as treatment continues. Even before these reactions have remitted spontaneously, they may often be controlled by careful adjustment of dosage form, amount of drug, or interval between doses.

Isolated instances of suppurative parotitis secondary to excessive dryness at the mouth, skin rashes, dilatation of the colon, paralytic ileus, and certain psychiatric manifestations such as delusions and hallucinations, plus one doubtful case of paraesthesia all of which may occur with any of the atropine-like drugs, have been reported rarely with trihexyphenidyl hydrochloride.

Patients with arteriosclerosis or with a history of idiosyncrasy to other drugs may exhibit reactions of mental confusion, agitation, disturbed behavior, or nausea and vomiting. Such patients should be allowed to develop a tolerance through the initial administration of a small dose and gradual increase in dose until an effective level is reached. If a severe reaction should occur, administration of the drug should be discontinued for a few days and then resumed at a lower dosage. Psychiatric disturbances can result from indiscriminate use (leading to overdosage) to sustain continued euphoria.

Potential side effects associated with the use of any atropine-like drugs include constipation, drowsiness, urinary hesitancy or retention, tachycardia, dilation of the pupil, increased intraocular tension, weakness, vomiting, and headache.

The occurrence of angle-closure glaucoma due to long-term treatment with trihexyphenidyl HCl has been reported.