PRESCRIBING INFORMATION

TRIHEXYPHENIDYL

Trihexyphenidyl Hydrochloride Tablets USP

2 mg and 5 mg

Antispasmodic

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Prescribing Information

Indications: The treatment of all forms of Parkinsonism (postencephalitic, arteriosclerotic, and idiopathic) as well as in the prevention or control of extrapyramidal disorders due to central nervous system drugs such as reserpine and the phenothiazines. These disorders are similar to those encountered in Parkinson's disease and include tremor, rigidity, and increased salivation, akathisia manifested by extreme restlessness, and dyskenesias characterized by spastic contractions and involuntary movements.

Precautions: Maintain patients with cardiac liver, kidney or hypertensive disorders under close observation. Patients undergoing prolonged therapy should be subjected to constant and careful long-term observation to avoid allergic and other untoward reactions. Trihexyphenidyl 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 parasympatholytic drugs and hence, require strict dosage regulation. Incipient glaucoma may be precipitated by trihexyphenidyl.

Adverse Effects: Dryness of mouth, blurred vision, dizziness, mild nausea or nervousness will be experienced by 30 to 50% of all patients. Isolated instances of suppurative parotitis secondary to excessive dryness of the mouth, skin rashes, dilatation of the colon, paralytic ileus, and certain psychiatric manifestations such as delusions and hallucinations, plus one doubtful case of paranoia, have been rarely reported with trihexyphenidyl. 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 a 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 untoward effects associated with the use of any atropine-like drugs include constipation, drowsiness, urinary hesitancy or retention, tachycardia, dilatation of the pupil, increased intraocular tension, weakness, vomiting, and headache.

Dosage: Should be individualized. The initial dosage should be low and then increased gradually, especially in patients over 60 years of age.

Parkinsonism: 1 mg orally the first day; increased by 2 mg daily at intervals of 3 to 5 days, up to 6 to 10 mg daily. Best tolerated in divided doses at mealtime.

Drug-Induced Parkinsonism: The size and frequency of doses of trihexyphenidyl needed to control drug-induced extrapyramidal reactions, attributable especially to reserpine and phenothiazine derivatives, must be determined empirically. The total daily dosage usually ranges between 5 and 15 mg although, in some cases, these reactions have been satisfactorily controlled on as little as 1 mg daily. It may be advisable to commence therapy with a single 1 mg dose. If the extrapyramidal manifestations are not controlled in a few hours, the subsequent doses may be progressively increased until satisfactory control is achieved. Satisfactory control may sometimes be more rapidly achieved by temporarily reducing the dosage of the tranquilizer or instituting trihexyphenidyl therapy and then adjusting dosage of both drugs until the desired ataractic effect is retained without onset of the extrapyramidal reactions.

It is sometimes possible to maintain the patient on a reduced trihexyphenidyl dosage after the reactions have remained under control for several days. Instances have been reported in which these reactions have remained in remission for long periods after therapy was discontinued.

Supplied: Each white tablet contains Trihexyphenidyl 2 mg or 5 mg. Available in bottles of 100.