APO-TRIHEX
Trihexyphenidyl Hydrochloride Tablets USP 2mg
Antiparkinsonian

Pharmacology: Trihexyphenidyl is an anticholinergic antiparkinsonian agent. It produces an atropine-like blocking action of parasympathetic-innervated peripheral structures including smooth muscle. It also exhibits a direct spasmolytic action and weak mydriatic, anti-sialogogue and cardiovagal blocking effects. In small doses, trihexyphenidyl depresses the CNS but larger doses cause cerebral excitement resembling the signs of atropine toxicity. Trihexyphenidyl is rapidly absorbed from the gastrointestinal tract. After oral administration, the onset of action occurs within 1 hour, peak effects last 2 to 3 hours and the duration of action is 6 to 12 hours. It is excreted in the urine probably as unchanged drug.

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 CNS 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 dyskinesias characterized by spastic contractions and involuntary movements.

Contraindications: Untreated urinary retention, closed-angle glaucoma, gastro-intestinal obstruction.

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. Trihexyphenidyl may cause anhidrosis. Caution should also be exercised during hot weather especially if given with other anticholinergic drugs. Incipient glaucoma may be precipitated by trihexyphenidyl. Pregnancy, lactation and children: Safe use in children, pregnant or lactation women has not been established. Geriatrics: Geriatric patients particularly over the age of 60 frequently develop increased sensitivity to parasympatholytic drugs and hence, require strict dosage regulation.
Occupational Hazards: Trihexyphenidyl may impair mental and/or physical abilities required for performance of hazardous tasks such as operating machinery or driving a motor vehicle.

Drug Interactions: CNS depressants: Trihexyphenidyl in small doses, may enhance the CNS depressant effects of drugs including alcohol, an anticonvulsants, barbiturates, MAO inhibitors, narcotic analgesics, phenothiazines and tricyclic antidepressants.
Anticholinergics: Trihexyphenidyl may enhance the anticholinergic effects of drugs including atropine, MAO inhibitors, tricyclic antidepressants and phenothiazines. Paralytic ileus, sometimes fatal, hyperthermia and heat stroke may occur. Advise patients to report gastrointestinal problems, fever or heat intolerance promptly.
Levodopa: When trihexyphenidyl is used in combination with levodopa, the dosage of each drug may have to be reduced.

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 gradual increase the 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. Withdrawal symptoms may occur in patients receiving large doses. Potential untoward effects associated with the use of any atropine like drugs include constipation, drowsiness, urinary hesitancy or retention, tachycardia, postural hypotension, dilatation of the pupil, increased intraocular tension, weakness, vomiting and headache.

Overdose: Symptoms: May be any of those seen in atropine poisoning. CNS depression, confusion, hallucinations, psychosis, ataxia, muscle weakness, dry mouth, mydriasis, blurred vision, palpitations, shock, convulsions, respiratory arrest, anhidrosis, hyperthermia, glaucoma, constipation.
Treatment: Maintain respiration, cardiac output and fluid and electrolyte balance. Give ipecac syrup and activated charcoal or perform gastric lavage if no contraindications exist. Ice bags may be used for hyperthermia. Control excitement with i.v diazepam. Propranolol may by used for arrhythmias. Physostigmine salicylate may be used when indicated to reverse convulsions, cardiac arrhythmias and hallucinations. It is not recommended for routine use or to reverse coma.

Dosage: Should be individualized. The initial dosage should be low and then increased gradually especially in patients over 60 years of age. Parkinsonism: 1mg orally the first day; increased by 2mg daily at intervals of 3 to 5 days, up to 6 to 10mg daily. Best tolerated in divided dose at mealtime. Drug induced parkinsonism: The size 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 15mg. Although, in some cases, these reactions have been satisfactorily controlled on as little as 1mg daily. It may be advisable to commence therapy with single 1mg 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.

Storage Conditions: Store below 30°C.

Supplied: Each round, flat-faced, bevelled edge white tablets, scored on one side and engraved “APO" over "TRM", other side plain contains trihexyphenidyl hydrochloride 2mg. Available in HDPE bottles of 100 tablets.

Manufacturer name and address:
Apotex Inc., 150 Signet Drive, Weston, Ontario, Canada M9L 1T9.

Product Registration Holder:
Pharmaforte (M) Sdn Bhd
2, Jalan PJU 3/49, Sunway Damansara, 47810, Petaling Jaya, Selangor.

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