Hexiphen™

Trihexyphenidyl Hydrochloride

Presentation
Hexiphen™ 2 Tablet: Each tablet contains Trihexyphenidyl Hydrochloride USP 2 mg.
Hexiphen™ 5 Tablet: Each tablet contains Trihexyphenidyl Hydrochloride USP 5 mg.

Pharmacodynamic Properties
Trihexyphenidyl Hydrochloride is an anticholinergic used in the symptomatic treatment of all etiologic groups of parkinsonism and drug induced extrapyramidal reactions (except tardive dyskinesia). Trihexyphenidyl Hydrochloride possesses both anticholinergic and antihistaminic effects, although only the former has been established as therapeutically significant in the management of parkinsonism.

Pharmacokinetic Properties
Trihexyphenidyl Hydrochloride is rapidly absorbed from the gastrointestinal tract. Half-life of Trihexyphenidyl Hydrochloride is 3.3-4.1 hours. Trihexyphenidyl Hydrochloride exerts a direct inhibitory effect upon the parasympathetic nervous system. It also has a relaxing effect on smooth musculature; exerted both directly upon the muscle tissue itself and indirectly through an inhibitory effect upon the parasympathetic nervous system.

Indications
Trihexyphenidyl Hydrochloride tablet is indicated as an adjunct treatment of all forms of parkinsonism (post encephalitic, arteriosclerotic & idiopathic). Additionally, it is indicated for the control of extrapyramidal disorders caused by central nervous system drugs such as dibenzoxazepines, phenothiazines, thioxanthenes & butyrophenones.

Dosage and Administration
Dose should be individualized. The initial dose should be low and then increased gradually, especially in patients over 60 years of age. Whether Trihexyphenidyl Hydrochloride may best be given before or after meals should be determined by the way of the patient reacts.

Idiopathic Parkinsonism
1 mg of Trihexyphenidyl Hydrochloride tablet may be administered at first day. Then the dose may be increased by 2 mg increments at intervals of three to five days.

Drug-Induced Parkinsonism
Commence therapy with a single 1 mg dose increase the total daily dosage to 5-15 mg range if the extrapyramidal manifestations are not controlled.

Concomitant Use with Levodopa
When Trihexyphenidyl Hydrochloride is used concomitantly with levodopa, the usual dose is 3-6 mg daily.

Contraindications
Contraindicated in patients with hypersensitivity to Trihexyphenidyl Hydrochloride or to any of the tablet ingredients. Trihexyphenidyl Hydrochloride is also contraindicated in patients with narrow angle glaucoma. Blindness after long-term use due to narrow angle glaucoma has been reported.

Precautions
Patients with cardiac, liver, or kidney disorders, or with hypertension, should closely be monitored. Since Trihexyphenidyl Hydrochloride has 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. Trihexyphenidyl Hydrochloride is not recommended for use in patients with tardive dyskinesia unless they have concomitant Parkinson's disease. Abrupt withdrawal of treatment for parkinsonism may result in acute exacerbation of parkinsonism symptoms; therefore, abrupt withdrawal should be avoided.

Side Effects
Minor side effects such as dryness of the mouth, blurring of vision, dizziness, mild nausea or nervousness. 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. Potential side effects are constipation, drowsiness, urinary hesitancy or retention, pupil dilation, increased intraocular tension, vomiting and headache.

Drug Interactions
Cannabinoids, barbiturates, opiates and alcohol may have additive effects with Trihexyphenidyl Hydrochloride and thus an abuse potential exists. Concurrent use of alcohol or other CNS depressants with Trihexyphenidyl Hydrochloride may cause increased sedative effects. It may be contraindicated in patients taking monoamine oxidase inhibitors & tricyclic antidepressants.

Use in Pregnancy and Lactation
Pregnancy: Pregnancy Category C.

Nursing mothers: It is not known whether the drug is excreted in human milk and therefore Trihexyphenidyl Hydrochloride should only be used if the expected benefit to the mother outweighs the potential risk to the infant.

Overdose
Overdosage with Trihexyphenidyl Hydrochloride produces typical central symptoms of atropine intoxication (the central anticholinergic syndrome). Signs & symptoms are: dilated and sluggish pupils, warm & dry skin, facial flushing, decreased secretions of mouth, pharynx, nose and bronchi, foul smelling breath, tachycardia etc. Neuropsychiatric signs such as delirium, disorientation, anxiety, hallucinations etc. The condition can progress to stupor, coma, paralysis, cardiac, respiratory arrest and death.

Storage
Store in a cool (below 30°C) and dry place, away from light. Keep out of the reach of children.

Packing
Hexiphen™ 2 Tablet: Each box contains 5 blister packs with each blister of 10 tablets.
Hexiphen™ 5 Tablet: Each box contains 3 blister packs with each blister of 10 tablets.

Manufactured by:
general GENERAL
Pharmaceuticals Ltd.
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