

Composition:

Heximax 2 Tablet: Each film coated tablet contains Trihexyphenidyl Hydrochloride BP 2 mg.

Heximax 5 Tablet: Each film coated tablet contains Trihexyphenidyl Hydrochloride BP 5 mg.

Pharmacology: Trihexyphenidyl HCl 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. Its therapeutic properties are similar to those of atropine although undesirable side effects are ordinarily less frequent and severe than with the latter.

Indications:

Heximax (Trihexyphenidyl HCl) is 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.

Dosage 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 allayed by mint candies, chewing gum or water. Abrupt withdrawal of treatment for Parkinsonism may result in acute exacerbation of Parkinsonism symptoms therefore, abrupt withdrawal should be avoided. Abrupt withdrawal of treatment may result in neuroleptic malignant syndrome (NMS). **Idiopathic Parkinsonism:** 1 mg of Trihexyphenidyl may be administered the first day. The dose may then 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 is used concomitantly with levodopa, the usual dose is 3-6 mg daily.

Contraindication: Trihexyphenidyl HCl is contraindicated in patients with hypersensitivity to Trihexyphenidyl HCl. Trihexyphenidyl HCl is also contra-indicated in patients with narrow angle glaucoma. Blindness after long-term use due to narrow angle glaucoma has been reported.

Warnings & Precautions: Patients to be treated with Trihexyphenidyl HCl should have a gonioscope evaluation prior to initiation of therapy and close monitoring of intraocular pressures. The use of anticholinergic drugs may precipitate angle closure with an increase in intraocular pressure. If blurring of vision occurs during therapy, the possibility of narrow angle glaucoma should be considered. Blindness has been reported due to aggravation of narrow angle glaucoma. Trihexyphenidyl HCl should be administered with caution in hot weather, especially when given concomitantly with other atropine like drugs to the chronically ill, alcoholics, those who have central nervous system disease or those who do manual labor in a hot environment. Anhidrosis may occur more readily when some disturbance of sweating already exists. If there is evidence of anhidrosis, the possibility of hyperthermia should be considered. Dosage should be decreased so that the ability to maintain body heat equilibrium via perspiration is not impaired. Severe anhidrosis and fatal hyperthermia have occurred with the use of anticholinergics under the conditions described above. **Neuroleptic Malignant Syndrome:** A potentially fatal symptom complex sometimes referred to as Neuroleptic Malignant Syndrome (NMS) has been reported in association with dose reduction or discontinuation of Trihexyphenidyl HCl.

Side effects: Minor side effects, such as dryness of the mouth, blurred vision, dizziness, mild nausea or nervousness will be experienced by 30 to 50 percent of all patients. Potential side effects associated with the use of any atropine like drugs, including Trihexyphenidyl HCl, include cognitive dysfunctions, including confusion and memory impairment, constipation, drowsiness, urinary hesitancy or retention, tachycardia, dilation of the pupil, increased intraocular pressure, choreiform movements, weakness, vomiting and headache. Exacerbation of parkinsonism with abrupt treatment withdrawal has been reported. Neuroleptic malignant syndrome with abrupt treatment withdrawal has been reported.

Use in Pregnancy and Lactation: Pregnancy Category C. 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.

Use in Children & adolescents: Heximax (Trihexyphenidyl Hydrochloride) should not be used in the treatment of children and adolescents under the age of 18 years.

Drug interactions: Cannabinoids, barbiturates, opiates and alcohol may have additive effects with Trihexyphenidyl HCl and thus an abuse potential exists. Concurrent use of alcohol or other CNS depressants with Trihexyphenidyl HCl may cause increased sedative effects. Monoamine oxidase inhibitors and tricyclic antidepressants possessing significant anticholinergic activity may intensify the anticholinergic effects of antidyskinetic agents because of the secondary anticholinergic activities of these medications. Prophylactic administration of anticholinergic agents, such as Trihexyphenidyl HCl as a prevention of drug-induced parkinsonism during neuroleptic therapy is not recommended. There may be an increased risk for the development of tardive dyskinesia during concomitant administration of anticholinergics and neuroleptics.

Overdose: In humans, doses up to 300 mg (5 mg/kg) have been ingested without fatalities or sequelae. However, rare cases of death associated with Trihexyphenidyl HCl over dosages taken in conjunction with other CNS-depressant agents have been reported or in patients with a compromised respiratory condition.

Storage

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

How Supplied:

Heximax 2 Tablet: Each box contains 3X10's tablets in Alu-Alu blister pack.

Heximax 5 Tablet: Each box contains 3X10's tablets in Alu-Alu blister pack.