

Composition:

Each Loxy (2 or 5) Tablet contains: Benzhexol hydrochloride (Trihexyphenidyl hydrochloride) 2 or 5 mg.

Mechanism of Action:

Trihexyphenidyl is an anticholinergic drug. It 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.

Pharmacokinetics:

Trihexyphenidyl HCl is well absorbed from the gastrointestinal tract. It disappears rapidly from the plasma and tissues and does not accumulate in the body during continued administration of conventional doses.

Indications:

Trihexyphenidyl is indicated in all forms of Parkinsonism (postencephalitic, arteriosclerotic and idiopathic). It is often useful as adjuvant therapy when treating these forms of Parkinsonism with levodopa.

Trihexyphenidyl is also indicated to control extrapyramidal disorders due to central nervous system drugs such as reserpine and the phenothiazines.

Contraindications:

- Hypersensitivity to the active substances or to any of the excipients.
- In patients with narrow angle glaucoma.

Warnings & Precautions:

Loxy should be treated with Loxy should have close monitoring of intraocular pressures at regular periodic intervals.

- Loxy should be used with caution in patients with:

1. Glaucoma, obstructive disease of the gastro-intestinal or genito-urinary tracts, and in elderly males with possible prostatic hypertrophy.

2. Hypertension, heart diseases, liver or kidney disorders.

- Loxy should be avoided or used with great caution in patients with myasthenia gravis.

Pregnancy & Lactation:

Pregnancy: Pregnancy category C. Trihexyphenidyl should not be used during pregnancy unless clearly necessary.

Lactation: Trihexyphenidyl should not be used during breast-feeding.

Drug Interactions:

- When trihexyphenidyl is given concomitantly with phenothiazines, clozapine, antihistamines, disopyramide, nefopam and amantadine it causes an increased antimuscarinic side-effects.

- Anticholinergic agents should be used with caution in patients who are receiving tricyclic antidepressants or monoamine oxidase inhibitors.

- Trihexyphenidyl may be antagonistic with the actions

of metoclopramide and domperidone on gastro-intestinal function.

- The absorption of levodopa may possibly be reduced when used in conjunction with trihexyphenidyl.

Side Effects:

About (30-50)% of patients experience minor side effects such as dry mouth, constipation, blurred vision, dizziness, nausea, urinary retention, skin rash, heart disorders. These reactions tend to become less pronounced as treatment continues.

Driving & Using Machines:

Trihexyphenidyl can cause blurring of vision, dizziness and mental confusion in some cases, therefore you should not drive a car or operate machinery when using Loxy.

Dosage & Administration:

Dosage should be individualized. The initial dose should be low and then increased gradually.

- Parkinsonism: 6-10 mg daily, given in divided doses 3 or 4 times per day.

- Post-encephalitic Parkinsonism: 12-15 mg daily, given in divided doses 3 or 4 times per day.

- Drug-induced Parkinsonism: 5-15 mg daily, given in divided doses 3 or 4 times per day.

- Drug-induced extrapyramidal disorder: 5-15mg daily, given in divided doses 3 or 4 times per day.

In initial therapy the dose should be 1 mg the first day, 2 mg the second day with further increases of 2 mg per day at three to five-day intervals until the optimum dose is reached.

When trihexyphenidyl is used concomitantly with levodopa the usual dose of each may need to be reduced.

Trihexyphenidyl dosage of 3-6 mg daily in divided doses, is usually adequate.

Elderly: Patients over 65 years of age require smaller amounts of the drug.

Overdose:

Symptoms of overdose include flushing and dryness of the skin, dilated pupils, dry mouth, tachycardia, rapid respiration, hyperpyrexia, hypertension, nausea, vomiting. Symptoms of CNS stimulation include confusion, hallucinations, paranoid and psychotic reactions, incoordination, delirium and occasionally convulsions. In severe overdose, CNS depression may occur with coma, circulatory and respiratory failure and death.

Treatment should always be supportive. Diazepam may be administered to control excitement and convulsions, but the risk of central nervous system depression should be considered.

Storage:

Keep out of reach of children. Store below 25° C.

Packaging:

Each Loxy (2 or 5) carton box contains 30 Tablets in three blister strips.

-A medication is a product which affects your health, and it's consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medication.
- The doctor and the pharmacist experts in medicine, it's benefits and risks.
- Do not repeat the same prescription without consulting your doctor.
KEEP THE MEDICATIONS OUT OF REACH OF CHILDREN
Council of Arab Health Ministers- Union of Arab Pharmacies

Reva Pharma for Pharmaceutical Industries - Idlib - Syria

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