Flexor®

Cyclobenzaprine Hydrochloride

Presentation
Flexor®5 tablet: Each tablet contains Cyclobenzaprine Hydrochloride USP 5 mg.
Flexor®10 tablet: Each tablet contains Cyclobenzaprine Hydrochloride USP 10 mg.

Description
Cyclobenzaprine Hydrochloride relieves skeletal muscle spasm of local origin without interfering with muscle function.

Indications and uses
Flexor is indicated as an adjunct to rest and physical therapy for relief of muscle spasm associated with acute, painful musculoskeletal conditions.
Improvement is manifested by relief of muscle spasm and its associated signs and symptoms, namely, pain, tenderness, limitation of motion, and restriction in activities of daily living.

Dosage and administration
The usual dose is 5-10 mg three times daily given by mouth. The daily dose should not exceed 60 mg. Treatment for more than 2 or 3 weeks is not recommended.
Dose in elderly: Therapy with Flexor in the elderly should be initiated with a 5 mg dose and titrated slowly upward.
Dose in hepatic impairment: Flexor should be used with caution in subjects with mild hepatic impairment starting with the 5 mg dose and titrating slowly upward. The use of Flexor in subjects with moderate to severe impairment is not recommended.

Side effects
The adverse reactions reported most frequently with Cyclobenzaprine Hydrochloride are drowsiness, dry mouth and dizziness. The incidence of these common adverse reactions is lower in the surveillance program than in the controlled clinical studies.

Precautions
Because of its atropine-like action, Cyclobenzaprine Hydrochloride should be used with caution in patients with a history of urinary retention, angle-closure glaucoma, increased intraocular pressure, and in patients taking anticholinergic medication.

Use in pregnancy and lactation
Pregnancy: Pregnancy category B. This drug should be used during pregnancy only if clearly needed.
Lactation: Caution should be exercised when Cyclobenzaprine Hydrochloride is administered to a nursing mother.

Pediatric use
Safety and effectiveness of Cyclobenzaprine Hydrochloride in pediatric patients below 15 years of age have not been established.

Contraindications
Hypersensitivity to any component of this product. Concomitant use of monoamine oxidase (MAO) inhibitors or within 14 days after their discontinuation.
Hyperpyretic crisis seizures, and deaths have occurred in patients receiving Cyclobenzaprine (or structurally similar tricyclic antidepressants) concomitantly with MAO inhibitor drugs.
Acute recovery phase of myocardial infarction, and patients with arrhythmias, heart block or conduction disturbances, or congestive heart failure. Hyperthyroidism.

Drug interactions
Cyclobenzaprine Hydrochloride may have life-threatening interactions with MAO inhibitors.
Cyclobenzaprine Hydrochloride may enhance the effects of alcohol, barbiturates, and other CNS depressants.

Overdose
Although rare, deaths may occur from over dosage with Cyclobenzaprine Hydrochloride. Signs and symptoms of toxicity may develop rapidly after Cyclobenzaprine overdose; therefore, hospital monitoring is required as soon as possible.

Commercial Pack
Flexor®5 tablet: Each box contains 10 blister strips of 10 tablets.
Flexor®10 tablet: Each box contains 10 blister strips of 10 tablets.

Manufactured by

incepta

Incepta Pharmaceuticals Ltd
Dhaka, Bangladesh

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