CYCLOBENZAPRINE HYDROCHLORIDE - cyclobenzaprine hydrochloride tablet
Alivio Medical Products, LLC

Drug Facts

Each film-coated tablet contains:

Cyclobenzaprine Hydrichloride, USP 10 mg

Usual Adult Dosage:

See package outsert for dosage information

This container is not intended for household use.

Dispense contents with a child-resistant closure

(as required) and in tight, light-resistant container

as defined in the USP.

Store at 20 to 25 C (68 to 77 F); excursions

permitted to 15 to 30 C (59 to 86 F) [See

USP Controlled Room Temperature]. KEEP THIS

AND ALL MEDICATION OUT OF THE REACH OF CHILDREN.

DESCRIPTION

Cyclobenzaprine hydrochloride, USP is a white, crystalline tricyclic amine salt with the empirical formula C20H21N-HCl and a molecular weight of 311.9.

CLINICAL PHARMACOLOGY

Cyclobenzaprine HCl relieves skeletal muscle spasm of local origin without interfering with muscle function. It is ineffective in muscle spasm due to central nervous system disease.

INDICATIONS AND USAGE

Cyclobenzaprine hydrochloride tablets,USP are indicated as an adjunct to rest and physical therapy for relief of muscle spasm associated with acute, painful muscoskeletal conditions.

CONTRAINDICATIONS

Hypersensitivity to any component of this product. Concomitant use of monoamine oxidase (MAO) inhibitors or within 14 days after their discontinuation.

WARNINGS

Serotonin Syndrome. The development of a potentially life-threatening serotonin syndrome has been reported with Cyclobenzaprine hydrochloride when used in combination with other drugs, such as selective

serotonin reuptake inhibitors (SSRIs), serotonin norepinephrine reuptake inhibitors (SNRIs), tricyclic antidepressants (TCAs), tramadol, bupropion, meperidine, verapimal,, or (MAO) inhibitors.

PRECAUTIONS

General. Because of its atropine - like action, cyclobenzaprine hydrochloride should be sued with caution

in patients with a history of urinary retention, angle-closure glaucoma, increased intraocular pressure and

in patients taking anticholinergic medication.

ADVERSE REACTIONS

Incidence of most common adverse reactions in the 2 double-blind, placebo controlled - 5 mg studies

(incidence of >3% on cyclobenzaprine hydrochloride 5 mg

DRUG ABUSE AND DEPENDENCE

Pharmacologic similarities among the tricyclic drugs require that certain withdrawal symptoms be

considered when cyclobenzaprine hydrochloride is administered, even though they have not been reported

to occur with this drug. Abrupt cessation of treatment after prolonged administration rarely may

produce nausea, headache and malaise. These are not indicative of addiction.

OVERDOSAGE

Although rare, deaths may occur from overdosage with cyclobenzaprine hydrochloride.

DOSAGE AND ADMINISTRATION

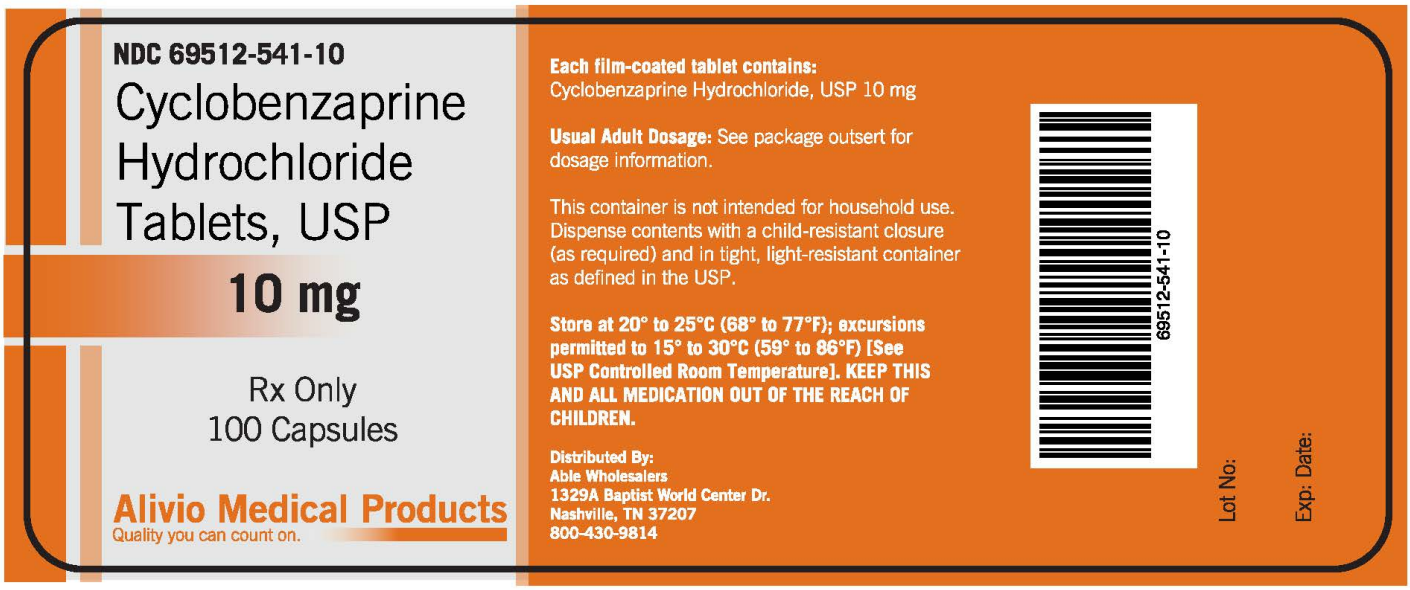
For most patients, the recommended dose of cyclobenzaprine hydrochloride tablets, USP is 5 mg three

times a day.

HOW SUPPLIED

Cyclobenzaprine hydrochloride tablets, USP 5 mg are supplied as butterscotch yellow-colored, capsule-

shaped, film-coated convex tablets, debossed with "AN40" on one side and plain on the other side.



CYCLOBENZAPRINE HYDROCHLORIDE

cyclobenzaprine hydrochloride tablet

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:69512-541

Route of Administration	ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CYCLOBENZAPRINE HYDROCHLORIDE (UNII: 0VE05JYS2P) (CYCLOBENZAPRINE - UNII:69O5WQQ5TI)	CYCLOBENZAPRINE HYDROCHLORIDE	10 mg in 10 mg

Inactive Ingredients

Ingredient Name	Strength
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	
POLYVINYL ALCOHOL (UNII: 532B59J990)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	yellow (Yellow (Butterscotch))	**Score**	no score
Shape	ROUND	**Size**	8mm
Flavor		**Imprint Code**	AN41
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69512-541-10	100 in 1 BOTTLE		
1		10 mg in 1 CAPSULE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA078218	10/01/2015	

Labeler - Alivio Medical Products, LLC (079670828)

Revised: 10/2015 Alivio Medical Products, LLC