

**CYCLOBENZAPRINE HYDROCHLORIDE- cyclobenzaprine hydrochloride tablet,
film coated**

Central Packaging

Cyclobenzaprine hydrochloride tablets are 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.

Cyclobenzaprine hydrochloride tablets should be used only for short periods (up to two or three weeks) because adequate evidence of effectiveness for more prolonged use is not available and because muscle spasm associated with acute, painful musculoskeletal conditions is generally of short duration and specific therapy for longer periods is seldom warranted.

Cyclobenzaprine hydrochloride tablets have not been found effective in the treatment of spasticity associated with cerebral or spinal cord disease, or in children with cerebral palsy.



CYCLOBENZAPRINE HYDROCHLORIDE

cyclobenzaprine hydrochloride tablet, film coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:80175-0400(NDC:43547-400)

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

Product Characteristics

Color	yellow	Score	no score
Shape	ROUND	Size	7mm
Flavor		Imprint Code	2632;V
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80175-0400-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2017	
2	NDC:80175-0400-6	60 in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2017	
3	NDC:80175-0400-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA077797	03/30/2017	

Labeler - Central Packaging (117617671)

Establishment

Name	Address	ID/FEI	Business Operations
Central Packaging, LLC		117617671	repack(80175-0400)

Revised: 2/2021

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