

**PRINORELAX 15 mg  
H.G.C. containing E.R. Pellets**

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11/1/2021  
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**1. INDICATIONS AND USAGE**

PRINORELAX (cyclobenzaprine hydrochloride extended-release capsules) 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, and limitation of motion.

Limitations of Use:

- PRINORELAX 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.
- PRINORELAX has not been found effective in the treatment of spasticity associated with cerebral or spinal cord disease or in children with cerebral palsy.

**2. DOSAGE AND ADMINISTRATION**

The recommended adult dose for most patients is one (1) PRINORELAX 15 mg capsule taken once daily. Some patients may require up to 30 mg/day, given as two (2) PRINORELAX 15 mg capsules taken once daily.

- It is recommended that doses be taken at approximately the same time each day.
- Use of PRINORELAX for periods longer than two or three weeks is not recommended [see *Indications and Usage (1)*].

Instruct patients to swallow PRINORELAX capsules intact. Alternatively, the contents of the PRINORELAX capsule may be sprinkled over applesauce and then swallowed. This method is appropriate only for patients able to reliably swallow the applesauce without chewing. Other foods have not been tested and should not be substituted for applesauce. Instruct the patient to:

- Sprinkle the contents of the capsule onto a tablespoon of applesauce and consume immediately without chewing.
- Rinse the mouth to ensure all of the contents have been swallowed.
- Discard any unused portion of the PRINORELAX capsules after the contents have been sprinkled on applesauce.

**3. DOSAGE FORMS AND STRENGTHS**

Hard Gelatin Capsules Containing Extended-release Pellets

**4. CONTRAINDICATIONS**

- Hypersensitivity to any component of this product. These adverse reactions may manifest as an anaphylactic reaction, urticaria, facial and/or tongue swelling, or pruritus. Discontinue PRINORELAX if a hypersensitivity reaction is suspected.
- 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.
- During the acute recovery phase of myocardial infarction, and in patients with arrhythmias, heart block or conduction disturbances, or congestive heart failure.
- Hyperthyroidism.

**5. WARNINGS AND PRECAUTIONS**

**5.1 Serotonin Syndrome**

The development of a potentially life-threatening serotonin syndrome has been reported with cyclobenzaprine 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, verapamil, or MAO inhibitors. The concomitant use of PRINORELAX with MAO inhibitors is contraindicated [see *Contraindications (4)*]. Serotonin syndrome symptoms may include mental status changes (e.g., confusion, agitation, hallucinations), autonomic instability (e.g., diaphoresis, tachycardia, labile blood pressure, hyperthermia), neuromuscular abnormalities (e.g., tremor, ataxia, hyperreflexia, clonus, muscle rigidity), and/or gastrointestinal symptoms (e.g., nausea, vomiting, diarrhea). Treatment with PRINORELAX and any concomitant serotonergic agents should be discontinued immediately if the above reactions occur and supportive symptomatic treatment should be initiated. If concomitant treatment with PRINORELAX and other serotonergic drugs is clinically warranted, careful observation is advised, particularly during treatment initiation or dose increases.

**5.2 Tricyclic Antidepressant-like Effects**

Cyclobenzaprine is structurally related to the tricyclic antidepressants, e.g., amitriptyline and imipramine. Tricyclic antidepressants have been reported to produce arrhythmias, sinus tachycardia, prolongation of the conduction time leading to myocardial infarction and stroke [see *Contraindications (4)*]. PRINORELAX may enhance the effects of alcohol, barbiturates, and other CNS depressants.

Some of the more serious central nervous system (CNS) reactions noted with the tricyclic antidepressants have occurred in short-term studies of cyclobenzaprine for indications other than muscle spasm associated with acute musculoskeletal conditions, and usually at doses somewhat greater than those recommended for skeletal muscle spasm. If clinically significant CNS symptoms develop, consider discontinuation of PRINORELAX.