

دواء
عقار
PRINORELAX

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Cyclobenzaprine Hydrochloride 30 mg
Hard Gelatin capsules containing Extended Release Pellets

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) Cyclobenzaprine Hydrochloride extended-release capsules 15 mg capsule taken once daily. Some patients may require up to 30 mg/day, given as one (1) PRINORELAX 30 mg capsule taken once daily or as two (2) Cyclobenzaprine Hydrochloride extended-release capsules 15 mg capsules taken once daily.

- a. It is recommended that doses be taken at approximately the same time each day.
- b. 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:

- c. Sprinkle the contents of the capsule onto a tablespoon of applesauce and consume immediately without chewing.
- d. Rinse the mouth to ensure all of the contents have been swallowed.
- e. 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

- a. 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.
- b. 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