

## PART III: CONSUMER INFORMATION

### **Pr PRO-CYCLOBENZAPRINE**

Cyclobenzaprine hydrochloride Tablets USP

**This leaflet is part III of a three-part "Product Monograph" and is a summary designed specifically for you to read. It will NOT tell you everything about PRO-CYCLOBENZAPRINE. Contact your doctor or pharmacist if you have any questions about the drug.**

### **ABOUT THIS MEDICATION**

#### **What the medication is used for:**

PRO-CYCLOBENZAPRINE (cyclobenzaprine hydrochloride) is a prescription medication used along with rest and physical therapy for relief of muscle spasm due to acute, painful musculoskeletal conditions.

#### **What it does:**

PRO-CYCLOBENZAPRINE relieves skeletal muscle spasm without interfering with muscle function. Your doctor may choose to use this medication for other conditions not listed here. If you're unsure why you are taking this medication, contact your doctor.

#### **When it should not be used:**

PRO-CYCLOBENZAPRINE should not be used by anyone who:

- is hypersensitive or allergic to the drug PRO-CYCLOBENZAPRINE or any ingredients of the medication (See section titled **What the nonmedicinal ingredients are**).
- is taking antidepressants known as monoamine oxidase (MAO) inhibitors or has taken them in the past 14 days.
- recently had a heart attack.
- has heart rhythm problems (arrhythmias)
- has heart failure.
- has an overactive thyroid gland (hyperthyroidism).

PRO-CYCLOBENZAPRINE tablets should not be used for more than two or three weeks. It is not known if it is safe or effective in children below 15 years of age.

#### **What the medicinal ingredient is:**

Cyclobenzaprine hydrochloride.

#### **What the nonmedicinal ingredients are:**

carnauba wax, colloidal silicon dioxide, ferric oxide yellow, hydroxypropyl methylcellulose, lactose anhydrous, magnesium stearate, microcrystalline cellulose, polyethylene glycol, starch and titanium dioxide.

#### **What dosage forms it comes in:**

PRO-CYCLOBENZAPRINE comes as a tablet containing 10 mg of cyclobenzaprine hydrochloride.

### **WARNINGS AND PRECAUTIONS**

BEFORE you use PRO-CYCLOBENZAPRINE talk to your doctor or pharmacist if you:

- have a history of eye problems including glaucoma
- have heart problems or have had a heart attack
- have liver problems
- have trouble emptying your bladder (urinary retention)
- are pregnant or plan to become pregnant. It is not known if this drug will harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if this drug passes into your breast milk. You and your healthcare provider should decide if you will take this drug or breastfeed.

Do not drive, operate machinery, or do other dangerous activities until you know how PRO-CYCLOBENZAPRINE affects you.

You should not drink alcohol until you know how PRO-CYCLOBENZAPRINE affects you. Taking this medication with alcohol or other medicines that depress your central nervous system can slow your thinking and physical response times.

PRO-CYCLOBENZAPRINE may affect the way other medicines work, and other medicines may affect how this drug works. **Tell your healthcare provider about all the medicines you take**

## IMPORTANT PLEASE READ

including prescription and non-prescription medicines, vitamins, and herbal supplements. It is especially important to tell your doctor if you are taking a medication listed under Interactions with this Medication.

### INTERACTIONS WITH THIS MEDICATION

Drugs that may interact with PRO-CYCLOBENZAPRINE include:

- alcohol, barbiturates and other medications that cause sedation
- MAO inhibitors (e.g., phenelzine, tranylcypromine)
- tricyclic antidepressants (e.g., amitriptyline, doxepin, imipramine, nortriptyline)
- medicines to treat depression, mood, anxiety, psychotic or thought disorders
- a pain medicine called tramadol or meperidine
- barbiturates or other medicines that depress your central nervous system (CNS depressants)
- a medicine that prevents nerve impulses (anticholinergic medicines)
- a medicine to help quit smoking called bupropion
- a blood pressure medicine called verapamil

If you are taking any of these drugs, speak with your doctor or pharmacist

### PROPER USE OF THIS MEDICATION

#### Usual dose:

The usual dosage of PRO-CYCLOBENZAPRINE tablets is 10 mg three times a day; with a range of 20 to 40 mg a day in divided doses. Dosage should not exceed 60 mg a day.

#### Overdose:

High doses may cause temporary confusion, disturbed concentration, transient visual hallucinations, agitation, hyperactive reflexes, muscle rigidity, vomiting, or hyperpyrexia. Based on the known pharmacological actions of the drug, over dosage may cause drowsiness, hypothermia, tachycardia and other cardiac rhythm abnormalities such as bundle branch block, ECG evidence of impaired conduction, and congestive heart

failure. Other manifestations may be dilated pupils, convulsions, severe hypotension, stupor, and coma.

If you think you have taken too much PRO-CYCLOBENZAPRINE, contact your healthcare professional, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

#### Missed Dose:

Talk to your doctor if you miss a dose.

### SIDE EFFECTS AND WHAT TO DO ABOUT THEM

These are not all the possible side effects you may feel when taking PRO-CYCLOBENZAPRINE. If you experience any side effects not listed here, contact your healthcare professional.

The most common side effects of PRO-CYCLOBENZAPRINE include:

- drowsiness
- dry mouth
- dizziness
- fatigue
- constipation
- nausea
- upset stomach

### Serious side effects and what to do about them

Symptom / effect		Talk to your healthcare professional		Stop taking drug and get immediate medical help
		Only if severe	In all cases	
<b>Less common</b>	Fast heartbeat (tachycardia), irregular or abnormal heartbeats (arrhythmias)			√
	Serotonin Syndrome - severe illness with some or			

### Serious side effects and what to do about them

Symptom / effect		Talk to your healthcare professional		Stop taking drug and get immediate medical help
		Only if severe	In all cases	
<b>Rare or Uncommon</b>	all of: agitation, hallucinations, coma or other changes in mental status; coordination problems or muscle twitching (overactive reflexes); fast heartbeat, high or low blood pressure; sweating or fever; nausea, vomiting, or diarrhea; muscle stiffness or tightness			√
<b>Rare or Uncommon</b>	Allergic reaction – including rash, hives, itching, and edema of the face and tongue, difficulty breathing.			√
<b>Rare</b>	Angle-closure Glaucoma [eye pain, changes in vision and swelling or redness in or around the eye]			√

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

### Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

*NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance*

### HOW TO STORE IT

Preserve in well-closed containers at room temperature 15°C to 30°C.

Keep out of reach and sight of children.

### MORE INFORMATION

**If you want more information about PRO-CYCLOBENZAPRINE:**

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Consumer Information by visiting the Health Canada website (<https://health-products.canada.ca/dpd-bdpp/index-eng.jsp>). or by contacting Pro Doc Ltée at 1-800-361-8559, [www.prodoc.qc.ca](http://www.prodoc.qc.ca) or [info@prodoc.qc.ca](mailto:info@prodoc.qc.ca).

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