

PART III: CONSUMER INFORMATION

^{Pr}**CYCLOBENZAPRINE**
(cyclobenzaprine hydrochloride)

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 CYCLOBENZAPRINE. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:
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:
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:
CYCLOBENZAPRINE should not be used by anyone who:

- is hypersensitive or allergic to the drug 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).

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:
Lactose Monohydrate USNF, Pregelatinized Starch USNF, Croscarmellose Sodium USNF, Magnesium Stearate USNF, Hypromellose USP, titanium dioxide USP, Macrogol USNF & Iron oxide yellow USNF.

What dosage forms it comes in:
CYCLOBENZAPRINE comes as a tablet containing 10 mg of cyclobenzaprine hydrochloride.

WARNINGS AND PRECAUTIONS

BEFORE you use 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 CYCLOBENZAPRINE affects you.

You should not drink alcohol until you know how 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.

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** including prescription and non-prescription medicines, vitamins, and herbal supplements. It is especially

IMPORTANT: PLEASE READ

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 CYCLOBENZAPRINE include:

- alcohol, barbiturates and other medications that cause sedation
- MAO inhibitors (e.g., phenelzine, tranylepromine)
- 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 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.

Over Dosage:

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.

In the event of an overdose, you should **IMMEDIATELY** contact either your doctor, the nearest hospital emergency department or poison control centre.

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 CYCLOBENZAPRINE. If you experience any side effects not listed here, contact your healthcare professional.

The most common side effects of CYCLOBENZAPRINE include:

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

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM				
Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and get immediate medical help
		Only if severe	In all cases	
Less common	Fast heartbeat (tachycardia), irregular or abnormal heartbeats (arrhythmias)			√
Rare or Uncommon	Serotonin Syndrome - severe illness with some or 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			√
Rare or Uncommon	Allergic reaction – including rash, hives, itching, and edema of the face and tongue, difficulty breathing.			√
Rare	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 help improve the safe use of health products for Canadians by reporting serious and unexpected side effects to Health Canada. Your report may help to identify new side effects and change the product safety information.

3 ways to report:

- Online at [MedEffect \(http://hc-sc.gc.ca/dhp-mps/medeff/index-eng.php\)](http://hc-sc.gc.ca/dhp-mps/medeff/index-eng.php);
- By calling 1-866-234-2345 (toll-free);
- By completing a Consumer Side Effect Reporting Form and sending it by:
 - Fax to 1-866-678-6789 (toll-free), or
 - Mail to:
Canada Vigilance Program
Health Canada,
Postal Locator 1908C
Ottawa, ON
K1A 0K9

Postage paid labels and the Consumer Side Effect Reporting Form are available at [MedEffect \(http://hc-sc.gc.ca/dhp-mps/medeff/index-eng.php\)](http://hc-sc.gc.ca/dhp-mps/medeff/index-eng.php).

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

HOW TO STORE IT

Store at room temperature between 15° - 30°C in tightly sealed containers.

Keep out of reach and sight of children.

MORE INFORMATION

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

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and

includes this document by visiting the Health Canada website (<http://hc-sc.gc.ca/index-eng.php>); calling the manufacturer at 1-866- 236-4076 or emailing quality@sanis.com.

This leaflet was prepared by Sanis Health Inc.,
1 President's Choice Circle, Brampton, Ontario, L6Y 5S5

Last Revised: April 18, 2017