

**PART III: CONSUMER INFORMATION**Pr **CLONIDINE****Clonidine Hydrochloride Tablets USP**

This leaflet is part III of a three-part "Product Monograph" published when CLONIDINE was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about CLONIDINE. Contact your doctor or pharmacist if you have any questions about the drug.

**ABOUT THIS MEDICATION****What the medication is used for:**

CLONIDINE Tablets are used to provide relief from hot flushes that may occur in women at menopause (change of life).

**What it does:**

CLONIDINE Tablets helps reduce the frequency, severity and duration of menopausal flushing (due to decreased estrogen levels).

**When it should not be used:**

Do not take this medicine if:

- You are allergic to clonidine hydrochloride or any other ingredients in CLONIDINE or have a rare hereditary problem of galactose intolerance or the Lapp lactose deficiency. CLONIDINE contains lactose.
- You have a severe slow heart rate; CLONIDINE can lower the heart and pulse rate.

**What the medicinal ingredient is:**

clonidine hydrochloride.

**What the important nonmedicinal ingredients are:**

The CLONIDINE (clonidine hydrochloride) tablet core contains the following inactive ingredients: Povidone, lactose monohydrate, magnesium stearate, microcrystalline cellulose, sodium starch glycolate.

The CLONIDINE tablet coating contains FD&C Blue #2, hypromellose, polyethylene glycol, polyvinyl alcohol - partially hydrolyzed, talc and titanium dioxide.

**What dosage forms it comes in:**

CLONIDINE is available in tablets. Each tablet contains 0.025 mg of clonidine hydrochloride.

**WARNINGS AND PRECAUTIONS**

BEFORE you use CLONIDINE talk to your doctor or pharmacist about any health conditions or problems you may have, including if you:

- have low blood pressure;
- have a slow heart rate, or heart failure, or irregular heart rate, or a recent heart attack;
- have or have had a stroke;
- have poor blood circulation to hands and feet such as

Raynaud's syndrome;

- are suffering from constipation;
- have kidney disease;
- have eye problems such as dry eye or wear contact lenses;
- have or have had depression;
- are pregnant or planning to become pregnant;
- are breast-feeding.

CLONIDINE is not to be used in patients under 18 years of age.

CLONIDINE may cause sleepiness, dizziness and fainting. Do not drive or operate machinery until you know how the drug affects you.

**INTERACTIONS WITH THIS MEDICATION**

Tell your doctor or pharmacist all the medicines you are taking including all prescription, non-prescription and natural health products, particularly if you are taking the following medicines:

- drugs that contain clonidine
- drugs that lower blood pressure such as water pills, betablockers, vasodilators, calcium antagonists, ACE-inhibitors
- drugs that slow the heart rate
- drugs for depression and MAO inhibitors
- alpha2 receptor blockers such as phentolamine
- methylphenidate
- indomethacin and other non-steroidal antiinflammatory agents
- barbiturates or other sedatives, including alcohol

**PROPER USE OF THIS MEDICATION**

Follow your doctor's instructions about when and how to take your medicine and always read the label.

**Usual dose:**

0.05 mg (two 0.025 mg tablets) twice a day. The tablets should be swallowed whole with water.

Do not stop taking CLONIDINE without talking to your doctor since stopping CLONIDINE suddenly may cause a severe withdrawal reaction, which in rare cases can cause death.

**Overdose:**

If you think you have taken too much CLONIDINE, contact your healthcare professional, hospital emergency department or regional poison control centre immediately, even if there are no symptoms.

**Missed Dose:**

If you forget to take a dose take one as soon as you remember, then carry on as before.

**SIDE EFFECTS AND WHAT TO DO ABOUT THEM**

Side effects may include: dry mouth, dizziness, tiredness, headache, nausea, vomiting, constipation, feeling weak (malaise), sleepiness, drowsiness and erectile dysfunction (trouble getting or keeping an erection), itchiness, rash, hive, hair loss.

If you experience any of these effects or any other effects not mentioned above and they continue or become troublesome, talk to your doctor or pharmacist.

**CLONIDINE can cause abnormal blood test results. CLONIDINE may also increase blood sugar, you may need to test your blood sugar more often.**

**SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN 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	
Disability of the eye to change its focus from near to distant objects	√		

*This is not a complete list of side effects. For any unexpected effects while taking CLONIDINE, contact your doctor or pharmacist.*

**SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN 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>Common</b>	<b>Blood pressure effects:</b> Fall in blood pressure on standing		√
	<b>Urinary effects:</b> Urinary difficulty or retention		√
<b>Uncommon</b>	<b>Allergic reaction:</b> Hives, swelling of lips, face or throat with difficulty breathing or speaking (signs of angioedema)		√
	<b>Hypersensitivity reactions:</b> Skin rash, skin eruption or other effect on the skin or eyes		√
	<b>Muscle or joint effects:</b> Muscle or joint pain and cramps of the lower limbs		√
	<b>Hallucination:</b> Problem with circulation to the fingers and toes (Raynaud's phenomenon)		√
<b>Rare</b>	<b>Heart effects:</b> Racing or irregular heart rate, slow heart rate		√
	<b>Blockage of the large bowel:</b> Colicky pain, constipation, vomiting, liver problems		√
	<b>Liver disorder:</b> Symptoms such as nausea, vomiting, dark/brown urine		√
<b>Not Known</b>	Confusion state		√

**HOW TO STORE IT**

The tablets should not be taken after the expiry date which is printed on the label.

CLONIDINE Tablets should be stored at room temperature (15°C - 30°C). Protect from moisture.

Keep this medicine out of the sight and reach of children.

**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 Program does not provide medical advice.

**MORE INFORMATION**

If you want more information about CLONIDINE:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (<https://health-products.canada.ca/dpd-bdpp/index-eng.js>); the manufacturer's website ([www.sivem.ca](http://www.sivem.ca)), or by calling 1-855-788-3153.

This leaflet was prepared by Sivem Pharmaceuticals ULC

Last revised: July 28, 2023.