

### **PART III: CONSUMER INFORMATION**

**TEVA-CLONIDINE** (Clonidine Hydrochloride) Tablet

This leaflet is part III of a three-part “Product Monograph” published when TEVA-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 TEVA-CLONIDINE. Contact your doctor or pharmacist if you have any questions about the drug.

#### **ABOUT THIS MEDICATION**

**What the medication is used for:**

TEVA-CLONIDINE tablets help reduce high blood pressure in patients that did not respond or who experienced unacceptable adverse events when using other medicines for high blood pressure.

**What it does:**

TEVA-CLONIDINE tablets belong to a group of medicines called antihypertensives which are used to reduce high blood pressure.

The clonidine hydrochloride ingredient of TEVA-CLONIDINE is a vasodilator which causes widening of the blood vessels and therefore an increase in blood flow. When there is less resistance to blood flow, blood pressure is lowered.

**When it should not be used:**

Do not take TEVA-CLONIDINE if you:

- Are hypersensitive or “allergic” to the active ingredient clonidine hydrochloride or any other ingredient in this product or component of the container, (see ‘**What the non-medicinal ingredients are:**’ section)
- Have a slow heart rate due to heart problems
- Have galactosaemia (a rare genetic condition causing galactose intolerance)

**What the medicinal ingredient is:**

clonidine hydrochloride.

**What the non-medicinal ingredients are:**

The TEVA-CLONIDINE 0.1 mg tablets contain: colloidal silicon dioxide, dibasic calcium phosphate, lactose monohydrate (spray dried), magnesium stearate and pregelatinized starch.

The TEVA-CLONIDINE 0.2 mg tablets contain: colloidal silicon dioxide, dibasic calcium phosphate, FD&C yellow #6 lake, lactose monohydrate (spray dried), magnesium stearate and pregelatinized starch.

**What dosage forms it comes in:**

Tablet; 0.1 mg (white), 0.2 mg (orange)

#### **WARNINGS AND PRECAUTIONS**

BEFORE you use TEVA-CLONIDINE, tell your doctor or pharmacist about any health conditions or problems you may have, including if you:

- have Raynaud’s disease or other circulation problems
- have any problems with circulation of blood to your brain
- have heart or kidney problems
- have a slow heart rate
- are suffering from constipation
- have symptoms of nerve disorders (such as altered sensation of the extremities or low blood pressure upon standing)
- have been told by your doctor that you have galactose intolerance
- are suffering from or have, in the past, suffered from depression
- are pregnant, planning to become pregnant or if you are breast feeding
- have pheochromocytoma (tumour of the adrenal gland)

TEVA-CLONIDINE is not recommended for use in children and adolescents (under the age of 18 years).

**Other warnings you should know about:**

TEVA-CLONIDINE tablets may cause drowsiness. If affected do not drive or operate machinery and avoid alcohol, sedatives or tranquilizers.

#### **INTERACTIONS WITH THIS MEDICATION**

Before taking TEVA-CLONIDINE, tell your doctor or pharmacist about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines, and:

- any other medicine containing clonidine
- diuretic tablets (commonly called water tablets e.g. furosemide)
- other medicines to treat high blood pressure (e.g. beta blockers)
- alpha blockers (e.g. phentolamine)
- tricyclic antidepressants (e.g. imipramine)
- major tranquilizers (e.g. chlorpromazine)
- non-steroidal anti-inflammatory agents (e.g. ibuprofen)
- vasodilators (e.g. sodium nitroprusside)
- calcium antagonists (e.g. verapamil, diltiazem hydrochloride)
- ACE inhibitors (e.g. captopril, lisinopril)
- cardiac glycosides (e.g. digoxin)
- tablets which cause drowsiness
- tablets to decrease appetite

## IMPORTANT: PLEASE READ

- neuroleptics (e.g. phenothiazines)

### PROPER USE OF THIS MEDICATION

Follow your doctor's instructions about when and how to take your medicine and always read the label. Do not change your dose or stop taking TEVA-CLONIDINE without first talking to your doctor.

#### Usual dose:

Initial dose: The usual starting dose is 0.1 mg tablet twice daily (morning and bedtime). Elderly patients may benefit from a lower initial dose.

Maintenance dose: After a period of 2 to 4 weeks, a higher dose may be needed until the desired response is achieved. In those instances where it is not possible to take the same dose of the drug in the morning and at bedtime, taking the larger dose at bedtime may help reduce the dry mouth and drowsiness side effects.

#### Overdose:

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Always take the labelled medicine container with you whether or not there are any TEVA-CLONIDINE tablets left.

#### Missed Dose:

If you forget to take your medicine, take your dose when you remember and then your next dose at the usual time. If you forget a dose completely, do not take two doses at the same time.

### SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Along with its intended action, any medication, including TEVA-CLONIDINE, may cause side effects. Most adverse events are mild and tend to diminish with continuation of therapy.

Side effects may include: dry mouth, dizziness, fatigue, headache, nausea, vomiting, constipation, malaise, sleep disorder, sedation and erectile dysfunction.

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

**With the exception of allergic reaction, you should not stop taking TEVA-CLONIDINE without first consulting**

**with your doctor as this may cause a severe withdrawal reaction which in rare cases can cause death.**

**TEVA-CLONIDINE can cause abnormal blood test results. They may indicate excess sugar in blood. Your doctor will decide when to perform blood tests and will interpret the results.**

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 seek immediate medical help
		Only if severe	In all cases	
Common	<b>Blood pressure effects:</b> Fall in blood pressure on standing		√	
	<b>Urinary effects:</b> Urinary difficulty or retention		√	
Uncommon	<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>		√	
Rare	<b>Problem with circulation to the fingers and toes (Raynaud's phenomenon)</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		√	

**IMPORTANT: PLEASE READ**

	nausea, vomiting, dark/brown urine			
<b>Not Known</b>	<b>Confusion state</b>		√	
	<b>Disability of the eye to change its focus from near to distant objects</b>	√		

Teva Canada Limited  
30 Novopharm Court  
Toronto, Ontario  
Canada, M1B 2K9

Last revised: April 25, 2014

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

**HOW TO STORE IT**

TEVA-CLONIDINE Tablets: Store between 15°C - 30°C.  
Protect from moisture.

Do not take this medicine after the expiry date which is printed on the packaging.

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

**REPORTING SUSPECTED SIDE EFFECTS**

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at [www.healthcanada.gc.ca/medeffect](http://www.healthcanada.gc.ca/medeffect)
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
  - Fax toll-free to 1-866-678-6789, or
  - Mail to: Canada Vigilance Program  
Health Canada  
Postal Locator 0701E  
Ottawa, ON K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at [www.healthcanada.gc.ca/medeffect](http://www.healthcanada.gc.ca/medeffect).

*NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.*

This document plus the full product monograph, prepared for health professionals can be found by contacting  
Teva Canada Limited  
at: 1-800-268-4127 ext. 1255005 (**English**)  
or 1-877-777-9117 (**French**)  
or [druginfo@tevacanada.com](mailto:druginfo@tevacanada.com)

This leaflet was prepared by: