

## **PATIENT MEDICATION INFORMATION**

### **READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE**

#### **Pr PRO-TELMISARTAN-HCTZ**

#### **Telmisartan/Hydrochlorothiazide Tablets**

Read this carefully before you start taking **PRO-TELMISARTAN-HCTZ** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **PRO-TELMISARTAN-HCTZ**.

#### **Serious Warnings and Precautions - Pregnancy**

- PRO-TELMISARTAN-HCTZ should not be used during pregnancy. Taking PRO-TELMISARTAN-HCTZ during pregnancy can cause injury or even death to your baby.
- If you discover that you are pregnant while taking PRO-TELMISARTAN-HCTZ, stop the medication and contact your healthcare professional as soon as possible.

#### **What is PRO-TELMISARTAN-HCTZ used for?**

- PRO-TELMISARTAN-HCTZ is used in adults to lower high blood pressure.

#### **How does PRO-TELMISARTAN-HCTZ work?**

PRO-TELMISARTAN-HCTZ contains a combination of 2 drugs, telmisartan and hydrochlorothiazide:

- Telmisartan is an angiotensin receptor blocker (ARB). You can recognize an ARB because its medicinal ingredient ends in “-SARTAN”. It works by blocking a substance in the body that causes blood vessels to tighten. It helps lower blood pressure.
- Hydrochlorothiazide is a diuretic or “water pill” that increases urination. It works by causing the kidneys to get rid of unneeded water and salt from the body into the urine. It also helps lower blood pressure.

This medicine does not cure high blood pressure. It helps to control it. Therefore, it is important to continue taking PRO-TELMISARTAN-HCTZ regularly even if you feel fine. Do not stop taking your medicine without talking to your healthcare professional.

#### **What are the ingredients in PRO-TELMISARTAN-HCTZ?**

Medicinal ingredients: Telmisartan and hydrochlorothiazide

Non-medicinal ingredients: Citric acid monohydrate, crospovidone, iron oxide yellow (for 80 mg/25 mg tablet only), lactose anhydrous, lactose monohydrate, macrogol poly (vinyl alcohol) grafted copolymer (polyvinyl alcohol, polyethylene glycol, anhydrous colloidal silica), magnesium stearate, meglumine, povidone, sodium hydroxide.

**PRO-TELMISARTAN-HCTZ comes in the following dosage forms:**

Tablets: 80 mg / 12.5 mg and 80 mg / 25 mg

**Do not use PRO-TELMISARTAN-HCTZ if:**

- you are allergic to telmisartan, hydrochlorothiazide or to any non-medicinal ingredient in PRO-TELMISARTAN-HCTZ (see **What are the ingredients in PRO-TELMISARTAN-HCTZ**).
- you are allergic to any sulfonamide-derived drugs (sulfa drugs), most of them have a medicinal ingredient that ends in “-MIDE”. This includes other diuretics (“water pills”).
- you have experienced an allergic reaction (angioedema) with swelling of the hands, feet or ankles, face, lips, tongue, throat, or sudden difficulty breathing or swallowing to any ARB (any drug in the same class as PRO-TELMISARTAN-HCTZ). Be sure to tell your healthcare professional that this has happened to you.
- you have difficulty urinating or produce no urine.
- you are pregnant or planning to become pregnant. Taking PRO-TELMISARTAN-HCTZ during pregnancy can cause injury and even death to your baby.
- you are breastfeeding. PRO-TELMISARTAN-HCTZ passes into breast milk.
- you are already taking a blood pressure-lowering medicine that contains aliskiren and you have diabetes or kidney problems.
- you have one of the following rare hereditary diseases:
  - Galactose intolerance;
  - Lapp lactase deficiency;
  - Glucose-galactose malabsorption.

This is because lactose is a non-medicinal ingredient in PRO-TELMISARTAN-HCTZ.

**To help avoid side effects and ensure proper use, talk to your healthcare professional before you take PRO-TELMISARTAN-HCTZ. Talk about any health conditions or problems you may have, including if you:**

- have a history of allergic reactions (angioedema).
- are allergic to penicillin.
- have narrowing of an artery or a heart valve.
- have heart failure.
- have diabetes. PRO-TELMISARTAN-HCTZ may cause low blood sugar levels.
- have liver or kidney problems.
- are taking any of the following:
  - blood pressure lowering medicines, such as aliskiren
  - an angiotensin-converting-enzyme inhibitor (ACEI)
  - beta blockers (i.e., acebutolol, metoprolol). Do NOT stop taking your beta-blocker without talking to your healthcare professional as this can cause serious side effects.

- have lupus, an autoimmune disease that can affect many parts of the body.
- have gout, a type of arthritis.
- are on dialysis.
- are dehydrated or if you suffer from excessive vomiting, diarrhea, or sweating.
- are taking a salt substitute that contains potassium, potassium supplements, or a potassium-sparing diuretic (a specific kind of “water pill” that makes your body keep potassium).
- are on a low-salt diet.
- are less than 18 years old.
- have been told by your healthcare professional that you have an intolerance to some sugars.
- have had skin cancer or have a family history of skin cancer.
- are taking a medicine that contains lithium. The combination with PRO-TELMISARTAN-HCTZ is not recommended.
- have a greater chance of developing skin cancer because you have light-coloured skin, get sunburned easily, or are taking medicines to suppress your immune system.

#### **Other warnings you should know about:**

##### **Risk of skin cancer:**

- PRO-TELMISARTAN-HCTZ contains hydrochlorothiazide. Treatment with hydrochlorothiazide may increase the risk of developing non-melanoma skin cancer. The risk is higher if you have been taking PRO-TELMISARTAN-HCTZ for many years (more than 3) or at a high dose.
- While taking PRO-TELMISARTAN-HCTZ:
  - Make sure to regularly check your skin for any new lesions. Check areas that are most exposed to the sun, such as the face, ears, hands, shoulders, upper chest and back.
  - Limit your exposure to the sun and to indoor tanning. Always use sunscreen (SPF-30 or higher) and wear protective clothing when going outside.

Talk to your healthcare professional immediately if you become more sensitive to the sun or UV light or if you develop an unexpected skin lesion (such as a lump, bump, sore, or patch) while you are taking PRO-TELMISARTAN-HCTZ.

**Increased sensitivity of the skin to sun:** Your skin may become sensitive to the sun while taking PRO-TELMISARTAN-HCTZ. Limit your exposure to the sun and to indoor tanning. Always use sunscreen (SPF-30 or higher) and wear protective clothing when going outside.

**Surgery:** Before surgery and general anesthesia (even at the dentist’s office), tell the healthcare professional that you are taking PRO-TELMISARTAN-HCTZ, as there may be a sudden fall in blood pressure associated with general anesthesia.

**Allergic Reactions / Angioedema:** Allergic reactions (angioedema) causing swelling of tissues under the skin, sometimes affecting the face and throat, have happened in people taking PRO-TELMISARTAN-HCTZ. These allergic reactions may happen at any time during treatment with PRO-TELMISARTAN-HCTZ and can be life threatening. Very rarely, cases have been fatal. If you experience an allergic reaction, stop taking PRO-TELMISARTAN-HCTZ and get immediate medical help.

**Blood Tests:** PRO-TELMISARTAN-HCTZ can cause abnormal blood test results. Your healthcare professional will decide when to perform blood tests and will interpret the results.

**Driving and using machines:** Before you perform tasks, which may require special attention, wait until you know how you respond to PRO-TELMISARTAN-HCTZ. Dizziness, lightheadedness, sensation that you, or the environment around you, is moving or spinning (Vertigo) or fainting can occur, especially after the first dose and when the dose is increased. If patients experience these adverse events, they should avoid potentially hazardous tasks such as driving or operating machinery.

**Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.**

#### **Serious Drug Interactions**

Do not take PRO-TELMISARTAN-HCTZ with other blood pressure lowering drugs, including diuretics (“water pills”), aliskiren-containing products, or angiotensin-converting-enzyme inhibitors (ACEI) if you have diabetes (type 1 or type 2) or serious kidney problems. When taken together with PRO-TELMISARTAN-HCTZ, they may cause very low blood pressure.

#### **The following may interact with PRO-TELMISARTAN-HCTZ:**

- adrenocorticotrophic hormone (ACTH) used to treat West Syndrome
- alcohol, barbiturates (sleeping pills), or narcotics (strong pain medications). They may cause low blood pressure and dizziness when you go from lying or sitting to standing up
- amphotericin B, an antifungal drug
- anticancer drugs, including cyclophosphamide and methotrexate
- Antidepressants, in particular selective serotonin reuptake inhibitors (SSRIs), including citalopram, escitalopram, and sertraline
- antidiabetic drugs, including insulin and oral medicines, such as repaglinide
- beta-blockers, medications for heart problems
- bile acid resins used to lower cholesterol, such as cholestyramine and colestipol resins
- calcium or vitamin D supplements
- corticosteroids used to treat joint pain and swelling
- digoxin, a heart medication
- drugs that slow down or speed up bowel function, including atropine,

- metoclopramide, and domperidone
- drugs used to treat epilepsy, including carbamazepine and topiramate
  - gout medications, including allopurinol and probenecid
  - lithium used to treat bipolar disease
  - nonsteroidal anti-inflammatory drugs (NSAIDs) used to reduce pain and swelling (such as ibuprofen, naproxen, and celecoxib)
  - medicines that increase the levels of potassium in your blood. These include:
    - potassium-sparing diuretics,
    - potassium supplements or
    - potassium-containing salt substitutes.
  - pressor amines, such as norepinephrine
  - skeletal muscle relaxants used to relieve muscle spasms, including tubocurarine
  - warfarin used to thin the blood to prevent blood clots

**How to take PRO-TELMISARTAN-HCTZ:**

- PRO-TELMISARTAN-HCTZ is not for initial therapy. You must first be stabilized on the individual components of PRO-TELMISARTAN-HCTZ (i.e., telmisartan and hydrochlorothiazide).
- Take PRO-TELMISARTAN-HCTZ exactly as prescribed. It is recommended to take your dose at about the same time everyday preferably in the morning.
- PRO-TELMISARTAN-HCTZ can be taken with or without food, but it should be taken the same way each day.
- PRO-TELMISARTAN-HCTZ tablets are for once-daily oral administration and should be swallowed whole with liquid.
- If PRO-TELMISARTAN-HCTZ causes upset stomach, take it with food or milk.

**Usual dose:**

Adults: One tablet daily.

**Overdose:**

If you think you, or a person you are caring for, have taken too much PRO-TELMISARTAN-HCTZ, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

**Missed Dose:**

If you have forgotten to take your dose during the day, carry on with the next one at the usual time. Do not double dose.

## What are possible side effects from using PRO-TELMISARTAN-HCTZ?

These are not all the possible side effects you may have when taking PRO-TELMISARTAN-HCTZ. If you experience any side effects not listed here, tell your healthcare professional.

Side effects may include:

- Back or leg pain, muscle cramps, joint pain, muscle spasms, pain, weakness, restlessness;
- Headache, anxiety, dizziness, pins and needles in your fingers;
- Diarrhea, constipation, nausea, vomiting, upset stomach, abdominal pain, flatulence, decreased appetite, enlargement of the glands in your mouth;
- Dry mouth;
- Rash, eczema, skin eruptions, bleeding under the skin, red patches on the skin;
- Drowsiness, insomnia, fatigue;
- Upper respiratory infection;
- Reduced libido.
- Very rare: Acute respiratory distress (signs include severe shortness of breath, fever, weakness, and confusion).

If you experienced breathing or lung problems (including inflammation or fluid in the lungs) following hydrochlorothiazide intake in the past or if you develop any severe shortness of breath or difficulty breathing after taking PRO-TELMISARTAN-HCTZ, seek medical attention immediately.

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>COMMON</b>			
<b>Low Blood Pressure:</b> dizziness, fainting, lightheadedness. May occur when you go from lying or sitting to standing up	✓		
<b>Anemia:</b> fatigue, loss of energy, weakness, shortness of breath		✓	
<b>Electrolyte Imbalance:</b> weakness, drowsiness, muscle pain or cramps, irregular heartbeat		✓	
<b>Chest Pain</b>		✓	

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>Non-Melanoma Skin Cancer:</b> lump or discoloured patch on the skin that stays after a few weeks and slowly changes. Cancerous lumps are red/pink and firm and sometimes turn into ulcers. Cancerous patches are usually flat and scaly.		✓	
<b>UNCOMMON</b>			
<b>Kidney Disorder:</b> change in frequency of urination, nausea, vomiting, swelling of extremities, fatigue		✓	
<b>Increased Blood Sugar:</b> frequent urination, thirst, and hunger	✓		
<b>Urinary Tract Infection (Cystitis):</b> frequent or painful urination, feeling unwell		✓	
<b>RARE</b>			
<b>Depression:</b> low mood, loss of interest in activities, change in appetite and sleep patterns	✓		
<b>Decreased or Increased Levels of Potassium in the Blood:</b> irregular heartbeat, muscle weakness and generally feeling unwell		✓	
<b>Liver Problems:</b> yellowing of the skin or eyes, dark urine, abdominal pain, nausea, vomiting, loss of appetite		✓	
<b>Low Blood Sugar (hypoglycemia):</b> shaky, irregular heartbeat, sweating, hunger, dizziness		✓	

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>Decreased Platelets:</b> bruising, bleeding, fatigue and weakness, small purple or red dots under the skin		✓	
<b>Hyponatraemia (decreased blood sodium):</b> nausea, vomiting, abdominal cramps, agitation, confusion and hallucinations		✓	
<b>Decreased White Blood Cells:</b> infections, fatigue, fever, aches, pains, and flu-like symptoms		✓	
<b>VERY RARE</b>			
<b>Acute respiratory distress (ARDS):</b> Severe shortness of breath, fever, weakness or confusion			✓
<b>Skin Reactions (Steven-Johnson Syndrome, Toxic Epidermal Necrolysis):</b> any combination of itchy skin rash, redness, blistering and peeling of the skin and/or of the lips, eyes, mouth, nasal passages or genitals, accompanied by fever, chills, headache, cough, body aches or joint pain, yellowing of the skin or eyes, dark urine			✓
<b>UNKNOWN</b>			
<b>Allergic Reaction:</b> rash, hives, swelling of the face, lips, tongue or throat, difficulty swallowing or breathing			✓



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>Rhabdomyolysis (breakdown of damaged muscle):</b> muscle pain that you cannot explain, muscle tenderness or weakness, dark brown (tea-coloured) urine			✓
<b>Heart Rhythm or Heart Rate Disturbances:</b> heart racing or skipping a beat		✓	
<b>Sepsis (blood poisoning):</b> chills, confusion, fever or low body temperature, shakiness, irregular heartbeat (including fatal outcome)		✓	
<b>Inflammation of the Pancreas:</b> abdominal pain that lasts and gets worse when you lie down, nausea, vomiting		✓	
<b>Eye Disorders:</b> <ul style="list-style-type: none"> <li>• <b>Myopia:</b> sudden near sightedness or blurred vision</li> <li>• <b>Glaucoma:</b> increased pressure in your eyes, eye pain</li> </ul> <b>Choroidal effusion (build up of liquid in your eye):</b> blind spots, eye pain, blurred vision			✓

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell 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 ([www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html](http://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.*

### Storage:

Store PRO-TELMISARTAN-HCTZ at room temperature (15°C to 30°C) in the package provided by your healthcare professional and protect from excessive moisture. Do not remove tablets from blisters until immediately prior to administration. Keep out of reach and sight of children.

### If you want more information about PRO-TELMISARTAN-HCTZ:

- 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://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); or by contacting Pro Doc Ltée : 1-800-361-8559, [www.prodoc.qc.ca](http://www.prodoc.qc.ca), [medinfo@prodoc.qc.ca](mailto:medinfo@prodoc.qc.ca).

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