PART III: CONSUMER INFORMATION

TELMISARTAN/HCTZ
Telmisartan/Hydrochlorothiazide tablets

Read this carefully before you start taking TELMISARTAN/HCTZ and each time you get a refill. This leaflet is a summary and will not tell you everything about TELMISARTAN/HCTZ. Talk to your doctor, nurse, or pharmacist about your medical condition and treatment and ask if there is any new information about TELMISARTAN/HCTZ.

ABOUT THIS MEDICATION

What the medication is used for:
TELMISARTAN/HCTZ is a combination of 2 drugs. It is used when 2 drugs are required to treat your high blood pressure.

What it does:
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 lowers blood pressure.
- Hydrochlorothiazide is a diuretic or "water pill" that increases urination. This lowers blood pressure.

This medicine does not cure high blood pressure. It helps to control it. Therefore, it is important to continue taking TELMISARTAN/HCTZ regularly even if you feel fine.

When it should not be used:
Do not take TELMISARTAN/HCTZ if you:

- Are allergic to telmisartan, hydrochlorothiazide or to any non-medical ingredient in the formulation.
- 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").
- 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 telmisartan). Be sure to tell your doctor, nurse, or pharmacist that this has happened to you.
- Have difficulty urinating or produce no urine
- Are pregnant or intend to become pregnant. Taking TELMISARTAN/HCTZ during pregnancy can cause injury and even death to your baby.
- Are breastfeeding. TELMISARTAN/HCTZ passes into breast milk.
- Are allergic to some sugars (lactose).
- Are already taking a blood pressure-lowering medicine that contains aliskiren and you have diabetes or kidney disease.
- Have one of the following rare hereditary diseases:
  - Galactose intolerance;
  - Lapp lactase deficiency;
  - Glucose-galactose malabsorption.

Because lactose is a non-medicinal ingredient in TELMISARTAN/HCTZ.

What the medicinal ingredients are:
Telmisartan and hydrochlorothiazide

What the non-medicinal ingredients are:
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.

What dosage forms it comes in:
Tablets 80 mg/12.5 mg and 80 mg/25 mg.

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions - Pregnancy

TELMISARTAN/HCTZ should not be used during pregnancy. If you discover that you are pregnant while taking TELMISARTAN/HCTZ, stop the medication and contact your doctor, nurse or pharmacist as soon as possible.

Before you use TELMISARTAN/HCTZ, talk to your doctor, nurse or pharmacist if you:

- Are allergic to any drug used to lower blood pressure including angiotensin converting enzyme (ACE) inhibitors, or penicillin.
- Have narrowing of an artery or a heart valve.
- Have heart failure.
- Have diabetes, liver or kidney disease.
- Are taking a medicine that contains aliskiren used to lower high blood pressure. The combination with TELMISARTAN/HCTZ is not recommended.
- Are taking an angiotensin-converting-enzyme inhibitor (ACEI).
- Have lupus or gout.
- 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").
- Are on a low-salt diet.
- Are less than 18 years old.
- Are having surgery and general anesthesia, (even at the dentist's office), tell the doctor or dentist that you are taking TELMISARTAN/HCTZ as there may be a sudden fall in blood pressure associated with general anesthesia.
- Have been told by your doctor that you have an intolerance to some sugars.

Hydrochlorothiazide in TELMISARTAN/HCTZ can cause Sudden Eye Disorders:

- Myopia: sudden nearsightedness or blurred vision.

- Glaucoma: an increased pressure in your eyes, eye pain. Untreated, it may lead to permanent vision loss.

These eye disorders are related and can develop within hours to weeks of starting TELMISARTAN/HCTZ.

You may become sensitive to the sun while taking telmisartan/hydrochlorothiazide. Exposure to sunlight should be minimized until you know how you respond.

Driving and using machines: Before you perform tasks which may require special attention, wait until you know how you respond to TELMISARTAN/HCTZ. Dizziness, lightheadedness, or fainting can especially occur after the first dose and when the dose is increased.

INTERACTIONS WITH THIS MEDICATION

As with most medicines, interactions with other drugs are possible. Tell your doctor, nurse, or pharmacist about all the medicines you take, including drugs prescribed by other doctors, vitamins, minerals, natural supplements, or alternative medicines.

The following may interact with TELMISARTAN/HCTZ:

- Adrenocorticotropic 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.
- Bile acid resins used to lower cholesterol, such as Cholestyramine and Colestipol Resins.
- Other blood pressure lowering drugs, including diuretics ("water pills"), aliskiren-containing products or angiotension-converting-enzyme inhibitors (ACEI). When taken in combination with TELMISARTAN/HCTZ, they may cause excessively low blood pressure.
- 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. Examples include ibuprofen, naproxen, and celecoxib.
- Skeletal muscle relaxants used to relieve muscle spasms, including tubocurare.
- Pressor Amines (e.g. norepinephrine)
- Warfarin.

PROPER USE OF THIS MEDICATION

Take TELMISARTAN/HCTZ exactly as prescribed. It is recommended to take your dose at about the same time everyday preferably in the morning.

TELMISARTAN/HCTZ can be taken with or without food, but it should be taken the same way each day. If TELMISARTAN/HCTZ causes upset stomach, take it with food or milk.

Usual adult dose:
The recommended dose of TELMISARTAN/HCTZ is one tablet daily.

Overdose:

If you think you have taken too much TELMISARTAN/HCTZ contact your doctor, nurse, pharmacist, 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.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

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
- visual disturbances
- upper respiratory infection
- reduced libido
- reduction in blood platelets, which increases risk of bleeding or bruising (small purple-red marks in skin or other tissue caused by bleeding)
- low blood magnesium level
- high blood calcium level
- increased PH (disturbed acid-base balance) due to low blood chloride level

If any of these affects you severely, tell your doctor, nurse or pharmacist.

TELMISARTAN/HCTZ can cause abnormal blood test results. 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, nurse or pharmacist**		**Stop taking drug and seek immediate medical help**
		Only if severe	**In all cases**	
Common	**Low Blood Pressure:** dizziness, fainting, lightheadedness May occur when you go from lying or sitting to standing up.	✓		
	Anemia: fatigue, loss of energy, weakness, shortness of breath.		✓	
	Electrolyte Imbalance: weakness, drowsiness, muscle pain or cramps, irregular heartbeat		✓	
	Chest pain		✓	
Uncommon	**Kidney Disorder:** change in frequency of urination, nausea, vomiting, swelling of extremities, fatigue		✓	
	Decreased White Blood Cells: infections, fatigue, fever, aches, pains, and flu-like symptoms		✓	
	Increased blood sugar: frequent urination, thirst, and hunger	✓		
	Urinary tract infection (Cystitis): frequent or painful urination, feeling unwell		✓	
Rare	**Depression:** Low mood, loss of interest in activities, change in appetite and sleep patterns	✓		

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM				
Symptom / effect		**Talk with your doctor, nurse or pharmacist**		**Stop taking drug and seek immediate medical help**
		Only if severe	**In all cases**	
	Decreased or increased levels of potassium in the blood: Irregular heartbeats, muscle weakness and generally feeling unwell		✓	
	Liver disorder: Yellowing of the skin or eyes, dark urine, abdominal pain, nausea, vomiting, loss of appetite		✓	
	Eye disorders: **- Myopia:** sudden near sightedness or blurred vision **- Glaucoma:** increased pressure in your eyes, eye pain			✓
	Low blood sugar: shaky, irregular heartbeat, sweating, hunger, dizziness		✓	
	Decreased Platelets: bruising, bleeding, fatigue and weakness		✓	
Unknown	**Allergic Reaction:** Rash, hives, swelling of the face, lips, tongue or throat, difficulty swallowing or breathing			✓
	Rhabdomyolysis: Muscle pain that you cannot explain, muscle tenderness or weakness or dark brown urine			✓
	Heart Rhythm or Heart Rate disturbances: heart racing or skipping a beat		✓	

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect		Talk with your doctor, nurse or pharmacist		Stop taking drug and seek immediate medical help
		Only if severe	In all cases	
	Sepsis (blood poisoning): chills, confusion, fever or low body temperature, shakiness, irregular heartbeat (including fatal outcome)		✓	
	Toxic Epidermal Necrolysis: severe skin peeling, especially in mouth and eyes			✓
	Inflammation of the Pancreas: abdominal pain that lasts and gets worse when you lie down, nausea, vomiting		✓	

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

HOW TO STORE IT

Store TELMISARTAN/HCTZ at room temperature (15-30°C) in the package provided by your doctor or pharmacist and protect from excessive moisture. Do not remove tablets from blisters or bottles until immediately prior to administration.

Store TELMISARTAN/HCTZ out of the reach and sight of children and pets.

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**
- **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, Ontario
    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.

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.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be found by contacting the sponsor, Sanis Health Inc., at:
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