

PART III: CONSUMER INFORMATION**PrVISKAZIDE®
(pindolol and hydrochlorothiazide)**

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

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

VISKAZIDE® lowers high blood pressure.

What it does:

VISKAZIDE® contains a combination of 2 drugs, pindolol and hydrochlorothiazide:

- Pindolol is a β -adrenergic-receptor-blocking agent. It dilates blood vessels which 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 VISKAZIDE® regularly even if you feel fine.

When it should not be used:**Do not take VISKAZIDE® if you:**

- Are allergic to pindolol, any beta blocker, hydrochlorothiazide, or to any non-medicinal ingredient in the formulation,
- Are allergic to any sulfonamide-derived drugs (sulfa drugs); most of them have a medicinal ingredient that ends in “-MIDE”,
- Have difficulty urinating or produce no urine,
- Suffer from, or have suffered in the past from, bronchial asthma, or other lung diseases or trouble in breathing,
- Suffer from a severe heart disease, Have had an alteration in the structure and function of the right ventricle of the heart caused by a primary disorder of respiratory system (called Cor pulmonale),
- Suffer from chest pain, mainly occurring at rest, or angina
- Suffer from irregular or unusually slow heartbeat (less than 45 to 50 beats per minute),
- Have had sudden loss of consciousness in the past,
- Suffer from severe blood flow disturbances of your blood vessels causing paleness or poor circulation in the arms and legs (cold hands or feet),
- Suffer from pheochromocytoma (a type of tumor of the adrenal glands),
- Are a pregnant woman,
- Are breastfeeding. VISKAZIDE® passes into breast milk.

If you need a procedure under anesthesia, tell your doctor that you are taking VISKAZIDE® because it should not be taken with anesthetics that lower heart function.

What the medicinal ingredients are:

Pindolol and hydrochlorothiazide

What the non-medicinal ingredients are:

Cellulose microcrystalline, magnesium stearate, pregelatinized starch, silica colloidal anhydrous.

What dosage forms it comes in:

Tablets; 10/25 and 10/50 mg

WARNINGS AND PRECAUTIONS**BEFORE you use VISKAZIDE® talk to your doctor, nurse, or pharmacist if you:**

- Are allergic to penicillin,
- Have diabetes
- Have liver or kidney disease,
- Have lupus or gout,
- Are dehydrated or suffer from excessive vomiting, diarrhea, or sweating,
- Are less than 18 years old,
- Suffer from milder forms of circulatory disturbances of blood vessels (symptoms such as paleness, cold hands or feet),
- Suffer from an overactive thyroid,
- Have chronic bronchitis and emphysema,
- Have psoriasis (a type of skin disease characterized by thickened patches of red/silver skin),
- Are taking or have recently taken any other drugs, including drugs obtained without a prescription,
- Are having any kind of surgery or dental treatment,
- Are experiencing eye problems (symptoms like dry, gritty or burning eyes).
- Have had skin cancer or have a family history of skin cancer.
- Have a greater chance of developing skin cancer because you have light-coloured skin, get sunburned easily, or are taking drugs to suppress your immune system.

Risk of skin cancer:

VISKAZIDE® contains hydrochlorothiazide. Treatment with hydrochlorothiazide may increase the risk of developing non-melanoma skin cancer. The risk is higher if you have been taking VISKAZIDE® for many years (more than 3) or at a high dose.

While taking VISKAZIDE®:

- 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 doctor immediately if you get more sensitive to the sun or UV light or if you develop an unexpected skin lesion (such as a lump, bump, sore, or patch) during the treatment.

Hydrochlorothiazide in VISKAZIDE® 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 VISKAZIDE®.

You may become sensitive to the sun while taking VISKAZIDE®. 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 VISKAZIDE®. 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 VISKAZIDE®:

- 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,
- Anesthetics used for surgery,
- Drugs blocking adrenaline effects,
- Antidiabetic drugs, including insulin and oral medicines,
- Bile acid resins used to lower cholesterol,
- Calcium or vitamin D supplements,
- Corticosteroids used to treat joint pain and swelling,
- Digoxin and digitalis glycosides, heart medications,
- 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,
- Other blood pressure lowering drugs. When taken in combination with VISKAZIDE®, they may cause excessively low blood pressure,
- Skeletal muscle relaxants used to relieve muscle spasms, including tubocurare,
- Drugs used to treat chest pain (angina pectoris), disturbances of heart rhythm,
- Drugs containing adrenaline or similar substances, such as nose and eye drops, cough medicines, or remedies for the common cold (substances that raise blood pressure),
- Ergot alkaloids, a class of drugs used in the prevention and treatment of migraine headaches,
- Drugs used to relieve heartburn and gastrointestinal ulcer (called cimetidine),
- Drugs used to treat anxiety and/or panic disorder, schizophrenia or psychosis,
- Fingolimod, a medicine used to treat multiple sclerosis.

PROPER USE OF THIS MEDICATION

Take VISKAZIDE® exactly as prescribed. It is recommended to take your dose at about the same time every day in the morning.

If VISKAZIDE® causes upset stomach, take it with food or milk.

Usual Adult dose:

One or two tablets once a day. Dosage is individualised for each patient.

Overdose:

If you think you have taken too much VISKAZIDE® contact your doctor, nurse, pharmacist, hospital emergency department or regional Poison control Centre immediately, even if there are no symptoms.

Overdose symptoms may include: abnormally low heartbeat, low blood pressure, low blood sugar; insufficient action of the heart to pump blood which may lead to loss of consciousness; irregular heart beat; heart failure; difficulty breathing with wheezing or coughing; shortness of breath; vomiting; convulsions (seizures); heart attack, coma and death.

Missed Dose:

If you have forgotten to take your dose during the day, carry on with the next one at the usual time. However, if it is almost time for the next dose, skip the missed dose and go back to your regular dosage schedule. Do not double doses.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Patients at the age of 65 or over may experience more side effects

than young patients. Close monitoring by your doctor may be required.

Side effects may include:

- muscle cramps, spasms, and pain, weakness, fatigue, restlessness
- dizziness, pins and needles in your fingers, headache
- abdominal pain, constipation, diarrhea, nausea, vomiting, decreased appetite, upset stomach, enlargement of the glands in your mouth
- reduced libido
- bleeding under the skin, rash, red patches on the skin

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

VISKAZIDE® 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.	✓		
	Decreased levels of potassium in the blood: irregular heartbeats, muscle weakness and generally feeling unwell.		✓	

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	
	Non-melanoma skin cancer: 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.		✓	
Uncommon:	Allergic Reaction: rash, hives, swelling of the face, lips, tongue or throat, difficulty swallowing or breathing.			✓
	Kidney Disorder: change in frequency of urination, nausea, vomiting, swelling of extremities, fatigue.		✓	
	Liver Disorder: yellowing of the skin or eyes, dark urine, abdominal pain, nausea, vomiting, loss of appetite.		✓	

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Symptom / effect	Talk with your doctor, nurse, or pharmacist		Stop taking drug and seek immediate medical help	
	Only if severe	In all cases		
	Increased blood sugar: frequent urination, thirst, and hunger.	✓		
	Electrolyte Imbalance: weakness, drowsiness, muscle pain or cramps, irregular heartbeat.	✓		
Rare	Decreased Platelets: bruising, bleeding, fatigue and weakness		✓	
	Decreased White Blood Cells: infections, fatigue, fever, aches, pains, and flu-like symptoms.		✓	
Very rare	Toxic Epidermal Necrolysis: severe skin peeling, especially in mouth and eyes.			✓
Unknown	Slow heart beat			✓
	Heart Rhythm Disturbance: racing or irregular heart beat		✓	
	Heart Failure: shortness of breath, leg swelling, exercise intolerance		✓	

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		
	Chest Pain, sudden and oppressive		✓	
	Eye Disorders: - Myopia: sudden near sightedness or blurred vision - Glaucoma: increased pressure in your eyes, eye pain			✓
	Anemia: fatigue, loss of energy, weakness, shortness of breath.		✓	
	Inflammation of the Pancreas: abdominal pain that lasts and gets worse when you lie down, nausea, vomiting.		✓	
	Coldness, burning, tingling or numbness in arms or legs.		✓	
	Difficulty breathing with wheezing or coughing.		✓	
	Hallucination: see or hear things that are not there.		✓	
Unknown	Tiredness	✓		
	Trembling	✓		
	Sleep disturbance	✓		
	Depression		✓	

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	
Excessive sweating	✓		
Aggravation of psoriasis (thick patches of red/silver skin).		✓	

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

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be found at:
<http://www.aralez.com>
 or by contacting the sponsor, Aralez Pharmaceuticals Canada Inc., at: 1-866-391-4503 (toll-free)

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HOW TO STORE IT

- Do not use after the expiry date shown on the box.
- Store in the original package, protect from light.
- **Keep out of the reach and sight 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
- 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.