PART III: CONSUMER INFORMATION

Pr Lozide®
(indapamide tablets)

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

ABOUT THIS MEDICATION

What the medication is used for:
Lozide® is used to treat mild to moderate high blood pressure.
Lozide® can be used by itself or with other medicines to treat that condition.

What it does:
Lozide® is a diuretic often called a "water pill". It increases urination. This lowers blood pressure. Lozide® affects the kidney's ability to reabsorb electrolytes.
This medicine does not cure high blood pressure. It helps to control it. Therefore, it is important to continue taking Lozide® regularly even if you feel fine.

When it should not be used:
Do not take Lozide® if you:
- Are allergic to indapamide or any other sulfonamide or to any non-medicinal ingredient in the formulation
- Have severe kidney disease
- Have severe liver disease or suffer from a condition called hepatic encephalopathy (a degenerative disease of the brain)
- Have low potassium levels in your blood
- Are taking drugs to treat heart rhythm disturbances (antiarrhythmics) that might cause severe cardiac arrhythmias
- Are breastfeeding. Lozide® passes into breast milk
- Are pregnant. Lozide® should not be used during pregnancy. If you become pregnant, discontinue use immediately and discuss with your doctor
- Have lactose intolerance or have hereditary galactose intolerance, glucose-galactose malabsorption or total lactase deficiency because Lozide® contains lactose

What the medicinal ingredient is:
Indapamide

What the non-medicinal ingredients are:
Lozide® 1.25 mg tablets:
glycerol, hydroxypropylmethyl cellulose, lactose monohydrate, macrogol 6000, magnesium stearate, maize starch, microcrystalline cellulose, pregelatinized starch, sunset yellow S aluminium lake, talc, and titanium dioxide.

Lozide® 2.5 mg tablets:
colloidal silica, corn starch, ethylcellulose, FD&C Red No. 3 lake, FD&C Yellow No. 6 lake and glycerol monooleate, lactose, magnesium stearate, polysorbate, povidone, pregelatinized corn starch, sodium benzoate, sodium carboxymethylcellulose, sucrose, talc, titanium dioxide, white beeswax.

What dosage forms it comes in:
Tablets of 1.25 mg or 2.5 mg.

WARNINGS AND PRECAUTIONS

BEFORE you use Lozide® talk to your doctor, nurse, or pharmacist if you:
- Are dehydrated or suffer from excessive vomiting, diarrhoea, or sweating
- Have diabetes, liver or kidney disease
- Have any congenital or a family history of heart rhythm problems
- Suffer from hyperparathyroidism (dysfunctioning of the parathyroid gland)
- Have systemic lupus erythematosus (SLE)
- Are malnourished
- Are elderly
- Have coronary artery disease, heart disease or heart failure
- Had a surgery called a Sympathectomy
- Suffer from gout
- have muscle disorders including muscle pain, tenderness, weakness or cramps,

A decrease in vision or eye pain could indicate the presence of fluid accumulation in the vascular layer of the eye or an increase of pressure in your eye. These manifestations typically occur suddenly within hours to weeks following the taking of Lozide®. This can lead to permanent vision loss, if not treated. If you have a history of penicillin or sulfonamide

allergies, you can be at higher risk of developing these manifestations.

Lozide® is not recommended for use in children.

You may become sensitive to the sun while taking Lozide®. Exposure to sunlight should be minimized.

Athletes should be aware that Lozide® contains an active ingredient, which may give a positive reaction in doping tests.

Driving and using machines: Before you perform tasks which may require special attention, wait until you know how you respond to Lozide®. Dizziness, lightheadedness, or fainting can especially occur after the first dose or when another antihypertensive agent is added.

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 Lozide®:

- ACTH (e.g. tetracosactide) for treatment of arthritis or inflammatory bowel disease
- 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.
- Allopurinol (to treat gout)
- Antibiotics such as moxifloxacin, erythromycin IV, ciprofloxacine, clarithromycin,
- Antifungal medications such as amphotericin B (IV), fluconazole
- Antimicrobial medications such as pentamidine
- Baclofen, a skeletal muscle relaxant
- Calcium tablets or other calcium supplements
- Ciclosporin, tacrolimus or other medications to depress the immune system after organ transplantation
- Drugs to treat heart rhythm disturbances (e.g. digoxin, quinidine, hydroquinidine, disopyramide, amiodarone, sotalol, ibutilide, dofetilide, flecainide)
- Drugs to treat high blood pressure, including angiotensin converting enzyme (ACE) inhibitors
- Drugs used to treat mental disorders such as anxiety and schizophrenia (e.g. clozapine, risperidone, pimozide, amisulpride, haloperidol, donepezil)
- Drugs used to treat depression, in particular selective serotonin reuptake inhibitors (SSRIs eg. paroxetine, sertraline, citalopram, escitalopram) and tricyclic antidepressants (imipramine)
- Iodinated contrast media
- Lithium used to treat bipolar disease
- Metformin, an oral medication for diabetes
- Nonsteroidal anti-inflammatory drugs (NSAIDs), such as ibuprofen, naproxen or celecoxib or high doses of acetylsalicylic acid (more than 3 g/day)
- Oral corticosteroids for treatment of asthma
- Potassium-sparing diuretics (e.g. amiloride, spironolactone, triamterene)
- Stimulant laxatives such as bisacodyl and senna
- Medicines for the treatment of cancer (e.g. vandetanib, oxliplatin)
- Anaesthetics (e.g. propofol, sevoflurane)
- Anagrelide (used to reduce elevated platelet counts)
- Medicines used to treat nausea and vomiting (e.g. ondansetron, domperidone)
- Papaverine (used to treat gastro-intestinal problems)
- Antiparasitic medicines used to treat certain types of malaria (e.g. chloroquine)
- Antihistamines used to treat allergic reactions , such as hay fever
- Methadone (used to treat addiction)

PROPER USE OF THIS MEDICATION

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

Lozide® is for oral use: swallow the tablet whole with water.

Usual Adult dose:
1.25 mg tablet a day.

Maximum dose:
2.5 mg a day
Your doctor may increase the dose to a maximum of 2.5 mg daily depending on your response to treatment after 4 to 8 weeks.
Recommended dose for the elderly: 1.25 mg tablet a day.
This dose may be adjusted depending on your kidney function.

Overdose:

If you think you have taken too much Lozide® 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:

- **Headache**
- **Pains in the stomach, back, chest**
- **Dizziness**
- **Fatigue, weakness**
- **Burning or prickling feeling in hands, arms, legs or feet**
- **Muscle cramps**
- **Vertigo**
- **Constipation, diarrhoea, nausea, vomiting**
- **Cough, dry mouth**
- **Swelling**
- **Rash, itching**

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

Lozide® 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 immedia-te medical help
		Only if severe	In all cases	
Common	**Electrolyte disturbances (low levels of sodium, potassium and/or chloride):** muscle weakness, pain or cramps, irregular heartbeat, weakness, generally feeling unwell.		√	
	Changes in heart rate: faster, slower or irregular heart beat		√	
	Hyperuricaemia: high uric acid levels in the blood, which may cause gout: pain, swelling and redness in the joints		√	
	Increased blood sugar: frequent urination, thirst, hunger.		√	

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 immedia-te medical help**
		Only if severe	**In all cases**	
Uncommo n	**Low blood pressure:** dizziness, fainting, lightheaded-ness. May occur when you move from lying down or sitting to standing up.		√	
Unknown	**Decreased White Blood Cells:** infections, fatigue, fever, aches, pains and flu-like symptoms.		√	

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Symptom / effect		**Talk with your doctor, nurse, or pharmacist**		**Stop taking drug and seek immedia-te medical help**
		Only if severe	**In all cases**	
	Eye Disorders: -Acute Myopia: sudden near sightedness or blurred vision. **-Visual impairment - Decrease in vision or pain in your eyes due to high pressure** (possible signs of fluid accumulatio n in the vascular layer of the eye or acute angle-closure glaucoma)			√
	Rhabdomy olysis: muscle pain that you cannot explain, muscle tenderness or weakness, dark brown urine.			√
	Decreased Platelets: Bruising or unusual bleeding from the skin or other areas, fatigue, weakness.		√	

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Symptom / effect		**Talk with your doctor, nurse, or pharmacist**		**Stop taking drug and seek immedia-te medical help**
		Only if severe	**In all cases**	
	Decreased Red Blood Cells (anemia): fatigue, shortness of breath, irregular heart rate, dizziness, headache, pale skin.		√	
	Liver disorder yellowing of the skin or eyes, dark urine, abdominal pain, nausea, vomiting, loss of appetite.		√	
	Kidney disorder: change in frequency of urination, nausea, vomiting, swelling of extremities, fatigue.		√	
	Inflammation of the pancreas: severe upper stomach pain that gets worse when you lie down, often with nausea and vomiting.			√

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 immedia-te medical help**
		Only if severe	**In all cases**	
	Allergic Reaction/ Angioedema (swelling of the face, lips, mouth, tongue or throat) which may cause difficulty in swallowing or breathing.			√
	Hypercalcaemia: high calcium levels in the blood, may cause loss of appetite, nausea, vomiting, constipation, stomach pain.			√
	Torsade de pointes: life-threatening irregular heart beat Record of the electrical activity of the heart (electrocardiogram (ECG)) showing a prolonged QT interval			√

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 immedia-te medical help**
		Only if severe	**In all cases**	
	Possible worsening of pre-existing lupus: a disease affecting the skin, joints and kidneys			√
	Hepatitis a liver disease which may cause nausea, vomiting, loss of appetite, feeling generally unwell, fever, itching, yellowing of the skin and eyes, light colored bowel motions, dark coloured urine			√

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 immedia-te medical help**
		Only if severe	**In all cases**	
	Severe skin reactions: Stevens Johnson Syndrome, Toxic epidermic necrolysis: skin rash, redness of the skin, blistering of the lips, eyes or mouth, skin peeling, accompanie d by fever, chills, headache, cough, body aches and generally feeling unwell			√

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

HOW TO STORE IT

Keep out of reach and sight of children.
Store at room temperature (15°C-30°C).
Do not use after the expiry date stated on the carton or blister.

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

Please consult your doctor, nurse or pharmacist with any questions or concerns you may have regarding your individual condition.

This document plus the full product monograph, prepared for health professionals can be found at:
http://www.servier.ca
or by contacting the sponsor, Servier Canada Inc., at:
1-800-363-6093
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