

PART III: CONSUMER INFORMATION

Pr **COVERSYL**[®]
Perindopril erbumine tablets

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

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

Your doctor can prescribe COVERSYL[®] to:

- treat mild to moderate **High Blood Pressure**,
- treat mild to moderate congestive **Heart Failure** along with other medications,
- **Reduce Cardiovascular Risk** in patients with high blood pressure and/or those who have suffered a heart attack and have stable coronary artery disease.

What it does:

COVERSYL[®] is an angiotensin converting enzyme (ACE) inhibitor. You can recognize ACE inhibitors because their medicinal ingredient ends in **'-PRIL'**.

This medicine does not cure your disease. It is important to continue taking COVERSYL[®] regularly even if you feel fine. Do not stop taking your medicine without the advice of your doctor.

When it should not be used:

Do not take COVERSYL[®] if you:

- Are allergic to perindopril erbumine or to any non-medicinal ingredient in the formulation.
- 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 ACE inhibitor or without a known cause. Be sure to tell your doctor, nurse, or pharmacist that this has happened to you.
- Are taking a drug containing the combination of sacubitril/valsartan, due to the increased risk of serious allergic reaction which causes swelling of the face or throat (angioedema) when taken with COVERSYL[®].
- Are already taking a blood pressure-lowering medicine that contains aliskiren (such as Rasilez) and you have diabetes or kidney disease.
- Have been diagnosed with hereditary angioedema: an increased risk of getting an allergic reaction that is passed down through families. This can be triggered by different factors, such as surgery, flu, or dental procedures.
- Are pregnant or intend to become pregnant.
Taking COVERSYL[®] during pregnancy can cause injury and even death to your baby.
- Are breastfeeding. COVERSYL[®] passes into breast milk.

- Are lactose intolerant or have one of the following rare hereditary diseases:
 - Galactose intolerance
 - Lapp lactase deficiency
 - Glucose-galactose malabsorption

Because lactose is a non-medicinal ingredient in COVERSYL[®].

- Are on dialysis or any other type of blood filtration.
Depending on the machine that is used, COVERSYL[®] may not be suitable for you.
- Have kidney problems where the blood supply to your kidneys is significantly reduced (renal artery stenosis).

What the medicinal ingredient is:

Perindopril erbumine

What the non-medicinal ingredients are:

Hydrophobic colloidal silica, lactose monohydrate, magnesium stearate and microcrystalline cellulose. The 4 and 8 mg tablets also contain chlorophyllin Aluminium Lake as a colorant.

What dosage forms it comes in:

Tablet: 2mg, 4mg (breakable) or 8mg.

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions - Pregnancy
COVERSYL[®] should not be used during pregnancy.
If you discover that you are pregnant while taking COVERSYL[®], stop the medication and contact your doctor, nurse, or pharmacist as soon as possible.

BEFORE you use COVERSYL[®] talk to your doctor, nurse or pharmacist if you:

- Are allergic to any drug used to lower blood pressure.
- Have recently received or are planning to get allergy shots for bee or wasp stings.
- Have narrowing of an artery or a heart valve.
- Have/ had a heart attack or a stroke.
- Are taking a medicine that contains aliskiren, such as RASILEZ, used to lower high blood pressure. The combination with COVERSYL[®] is not recommended.
- Are taking an angiotensin receptor blocker (ARB). You can recognize an ARB because its medicinal ingredient ends in "-SARTAN".
- Have diabetes, liver or kidney disease.
- Are on dialysis.
- Are dehydrated or 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 receiving gold (sodium aurothiomalate) injections.

- Are less than 18 years old.
- Are on LDL Apheresis (a treatment to lower the LDL cholesterol in the blood).
- Have systemic lupus erythematosus (SLE).
- Have a skin condition known as scleroderma or “hard skin” (thickening of the skin).
- Have abnormally increased levels of a hormone called aldosterone in your blood (primary aldosteronism).

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

If you are going to have surgery and will be given an anesthetic, be sure to tell your doctor or dentist that you are taking COVERSYL®.

Driving and using machines: Before you perform tasks which may require special attention, wait until you know how you respond to COVERSYL®. 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 COVERSYL®:

- Agents increasing serum potassium, such as a salt substitute that contains potassium, potassium supplements, or a potassium-sparing diuretic (a specific kind of “water pill”).
- Allopurinol used to treat gout.
- Antidiabetic drugs, including insulin, gliptins and oral medicines.
- Baclofen (a skeletal muscle relaxant).
- Blood pressure-lowering drugs, including diuretics (“water pills”), aliskiren-containing products (e.g. RASILEZ), or angiotensin receptor blockers (ARBs).
- Estramustine (used in cancer therapy).
- Lithium used to treat bipolar disorder.
- Nonsteroidal anti-inflammatory drugs (NSAIDs), used to reduce pain and swelling. Examples include aspirin, ibuprofen, naproxen, and celecoxib.
- Other blood pressure lowering drugs, including diuretics (“water pills”). When taken in combination with COVERSYL® they may cause excessively low blood pressure.
- Vasodilators including nitrates (products that make the blood vessels become wider).
- Digoxin, a heart medication.
- Procainamide used to treat irregular heartbeats.
- Dextran sulphate, special intravenous fluid used to counteract life-threatening low blood pressure.
- Gentamicin, an antibiotic.

- Tricyclic antidepressants.
- Anaesthetics.
- Medications for mental disorders.
- Treatment for bee and wasp allergies.
- Gold salts for the treatment of rheumatoid arthritis.
- Trimethoprim (for the treatment of infections).
- Tacrolimus (for the treatment of auto-immune disorders or following transplant surgery).
- Neutral endopeptidase (NEP) inhibitors. The combination with COVERSYL is not recommended.
- Sirolimus, everolimus, temsirolimus and other drugs belonging to the class of mTOR inhibitors (used to avoid rejection of transplanted organs)

PROPER USE OF THIS MEDICATION

Take COVERSYL® exactly as prescribed.

Tablets should be swallowed whole with a glass of water **in the morning**. It is recommended to take your dose before a meal. Only the 4 mg tablet may be broken.

Usual Adult dose:

Dosage must be individualised and adjusted for the elderly and patients with kidney disease.

High Blood Pressure

For patients who are not taking diuretics (water pills)

Usual initial dose: 4 mg once a day.

Usual maintenance dose: 4 mg to 8 mg once a day.

Your doctor will monitor your blood pressure. If you are having high blood pressure in the hours before you take your dose, a twice a day schedule may be required.

For patients who are taking diuretics (water pills)

Your doctor may stop the diuretic for 2 to 3 days while you are given the initial doses of COVERSYL®. The doctor will decide the best COVERSYL® dosage for you to take. They may start with 2 mg once a day.

In elderly patients, the starting dose should be 2 mg once a day. If necessary, your doctor may increase the dose to 4 mg daily and then to 8 mg in one or two divided doses depending on your kidney function.

Heart Failure

Usual initial dose: 2 mg once a day.

In most cases, the dose may be increased to 4 mg once a day.

In the elderly, the usual dose is used.

Reduce Cardiovascular Risk

Usual initial dose: 4 mg once a day for 2 weeks.

Usual maintenance dose: 8 mg once a day.

In elderly patients, the initial dose should be 2 mg once a day for the first week, followed by 4 mg once a day the second week and 8 mg once a day thereafter if tolerated as the usual maintenance dose. The doctor should make adjustments at intervals of at least 2 to 4 weeks.

Overdose:

If you think you have taken too much COVERSYL® 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:

- Dizziness,
- Drowsiness, fatigue, weakness,
- Cough (often described as dry and irritating, usually is worse at night or when lying down), upper respiratory infection,
- Rash,
- Headache, ringing in the ears,
- Abdominal pain, nausea, disturbed digestion, diarrhea,
- Back pain,
- Loss of taste or metallic taste in your mouth.

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

COVERSYL® 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	Angina: Chest pain.			✓
	Palpitations: irregular heartbeats.	✓		
	Persistent Cough.		✓	
	Increased Levels of Potassium in the Blood: irregular heartbeat, muscle weakness and generally feeling unwell.		✓	
	Electrolyte Imbalance: weakness, drowsiness, muscle pain or cramps, irregular heartbeat.		✓	
	Low Blood Pressure: dizziness, fainting, light-headedness. May occur when you go from lying or sitting to standing up.	✓		
	Edema: swelling of the hands, ankles or feet.	✓		
	Depression: feeling sad, not interested in usual activities, weight change and sleep disruptions.	✓		
Uncommon	Allergic Reaction: rash, hives, swelling of the face, lips, tongue or throat, difficulty swallowing or breathing (angioedema).			✓

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 White Blood Cells: Infections, fatigue, fever, aches, pains, and flu-like symptoms.		✓	
Decreased Platelets: Bruising, bleeding, fatigue and weakness.		✓	
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.		✓	
Myocardial Infarction: heart attack, chest pain.			✓
Cerebrovascular accident/ Stroke: Slurring speech, blurred vision, face drooping.			✓
Erectile dysfunction.	✓		
Circulation problems.	✓		
Severe abdominal pain with or without nausea or vomiting.		✓	
Unusual skin irritation.	✓		
Mood disturbances.	✓		
Sleep disturbances.	✓		

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	
Pemphigoid/ Pemphigus: Formation of blister clusters over the skin.			✓
Rare		✓	
Very rare			✓
Psoriasis Aggravation.		✓	
Inflammation of the Pancreas: Abdominal pain that lasts and gets worse when you lie down, nausea and vomiting (pancreatitis).			✓
SIADH (syndrome of inappropriate antidiuretic hormone secretion): Concentrated urine (dark in colour), feel or are sick, have muscle cramps, confusion and fits (seizures) which may be due to inappropriate secretion of ADH (anti-diuretic hormone).		✓	

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

HOW TO STORE IT

Keep out of reach and sight of children.

Store at room temperature (15-30°C).

Protect from elevated humidity.

Do not use after the expiry date stated on the carton, blister or bottle.

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, ON K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available in 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 at www.servier.ca or by contacting the sponsor, Servier Canada Inc., at: 1-800-363-6093

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