

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

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 this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **COVERSYL**.

Serious Warnings and Precautions

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

What is **COVERSYL** used for?

COVERSYL is used in adults to:

- Treat mild to moderate **High Blood Pressure**
- Treat mild to moderate **Heart Failure** along with other medications
- **Lower the risk of heart attacks** in patients with high blood pressure and/or those who have suffered a heart attack and have a certain type of heart disease (coronary artery disease).

How does **COVERSYL** work?

COVERSYL belongs to a class of medicines called angiotensin converting enzyme (ACE) inhibitor. You can recognize ACE inhibitors because their medicinal ingredient ends in '-PRIL'. **COVERSYL** works by relaxing the blood vessels so blood can flow more easily. This helps to lower blood pressure. 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 healthcare professional.

What are the ingredients in **COVERSYL**?

Medicinal ingredients: Perindopril erbumine

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

COVERSYL comes in the following dosage forms:

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

Do not use **COVERSYL** if you:

- are allergic to perindopril erbumine or to any non-medicinal ingredient in **COVERSYL** (see What are the ingredients in **COVERSYL**?)
- have had an allergic reaction (angioedema) with swelling of the hands, feet, ankles, face, lips, tongue and throat or sudden difficulty breathing or swallowing:

- to any other ACE inhibitor
 - where the reason is not known (idiopathic angioedema)
- have been diagnosed with hereditary angioedema (an increased risk of getting an allergic reaction that is passed down through your family)
- are taking a medicine for heart failure containing sacubitril/ valsartan. Taking COVERSYL with sacubitril/ valsartan increases the risk of serious allergic reaction (angioedema). You must wait at least 36 hours after your last dose of sacubitril/valsartan before starting COVERSYL
- have diabetes or kidney disease and are already taking a blood pressure lowering medicine that contains aliskiren
- are pregnant or planning to become pregnant
- are breastfeeding. COVERSYL passes into breast milk
- are lactose intolerant (as COVERSYL contains lactose) or have one of the following rare hereditary diseases:
 - Galactose intolerance
 - Lapp lactase deficiency
 - Glucose-galactose malabsorption
- are on dialysis or receive other type of blood filtration. Depending on the treatment that is used, COVERSYL may not be suitable for you
- have a narrowing of the blood vessels to one or both kidneys (renal artery stenosis)

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

- have a history of allergic reactions (angioedema)
- are of African origin
- have recently received or are planning to get allergy shots for bee or wasp stings
- have any of the following health problems:
 - narrowing of an artery or a heart valve
 - liver problems
 - diabetes or any kidney problems
 - low blood pressure
 - systemic lupus erythematosus (SLE), an autoimmune disease that can affect many parts of the body
 - a skin condition known as scleroderma or “hard skin” (thickening of the skin)
 - a condition in which your body releases too much of the hormone aldosterone in your blood (primary aldosteronism)
- have had a heart attack or stroke
- are taking any of the following medicines:
 - medicines used to lower blood pressure:
 - aliskiren
 - angiotensin receptor blocker (ARB). You can recognize an ARB because its medicinal ingredient ends in "-SARTAN"
 - medicines containing a neutral endopeptidase inhibitor (e.g., sacubitril) to treat heart failure
 - anti-cancer or medicines used to prevent organ rejection after a transplant such as temsirolimus, everolimus and sirolimus. These medicines may increase the risk of having an allergic reaction (angioedema)

- medicines used to manage diabetes (dipeptidyl peptidase IV (DPP-IV) inhibitors). You can recognize a DPP-IV inhibitor because its medicinal ingredient ends in “-GLIPTIN”
- medicines which may affect the blood cells, such as:
 - allopurinol - used to treat gout (a type of arthritis)
 - procainamide - used to treat irregular heartbeats
- are on a low-salt diet
- are on dialysis
- are dehydrated or suffer from excessive vomiting, diarrhea, or sweating
- are at risk for developing high levels of potassium in your blood. This can be serious and can happen if you are taking:
 - a salt substitute that contains potassium
 - potassium supplements
 - a kind of “water pill” (potassium-sparing diuretic) that makes your body hold onto potassium such as spironolactone, eplerenone, triamterene or amiloride)
 - other medicines that may increase potassium in your blood such as trimethoprim, an antibiotic used to treat bacterial infections
- are receiving gold salts (sodium aurothiomalate) given by injection
- are on a treatment to lower cholesterol in the blood (LDL Apheresis)

Other warnings you should know about:

COVERSYL can cause serious side effects, including:

- **Allergic reaction / Angioedema:** Allergic reactions (angioedema) causing swelling of tissues under the skin, sometimes affecting the face and throat, have happened in people taking COVERSYL. These allergic reactions may happen at any time during treatment and can be life threatening. Very rarely, cases have been fatal. If you experience an allergic reaction, stop taking COVERSYL and get immediate medical help.
- **Hypotension (low blood pressure):** You may feel dizzy or light-headed:
 - in the first few days after you start taking COVERSYL or when your dose is increased.
 - when you exercise
 - when the weather is hot

You should lie down if this happens. If you faint, stop taking COVERSYL and talk to your healthcare professional.

- **Blood disorders:** ACE inhibitors, such as COVERSYL, may cause:
 - neutropenia / Agranulocytosis (decrease in white blood cells)
 - thrombocytopenia (low blood platelets)
 - anaemia (low red blood cells)
- **Hypoglycemia (low blood sugar):** COVERSYL may cause low blood sugar in patients with:
 - diabetes who are taking oral antidiabetic medicines or insulin.
 - kidney problems

You should closely monitor your blood sugar level, especially during the first month of your treatment with COVERSYL.

See the **Serious side effects and what to do about them table**, below, for more information on these and other serious side effects.

Cough: You may develop a dry and persistent cough while taking COVERSYL. This usually goes away once you stop taking COVERSYL or when the dose is lowered. Tell your healthcare professional if you experience this symptom.

Increased sensitivity of the skin to sun: Your skin may become sensitive to the sun while taking COVERSYL. 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 or general anaesthesia (even at the dentist's office), tell your healthcare professional that you are taking COVERSYL. You may experience a sudden fall in blood pressure when you are under general anaesthesia.

Blood tests: Your healthcare professional may do blood tests before you take COVERSYL and/or during treatment. These tests may check:

- the level of red and white blood cells and platelets in your body.
- that your liver or kidneys are working properly.
- the potassium levels in your blood.

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

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

The following may interact with COVERSYL:

- medicines that lower your blood pressure. These include:
 - Angiotensin-Converting Enzyme (ACE) inhibitors
 - diuretics ("water pills")
 - aliskiren-containing medicines
 - Angiotensin Receptor Blockers (ARBs)
 - beta blockers
- medicines that can increase the levels of potassium in your blood. These include:
 - potassium-sparing medicines (such as spironolactone, eplerenone, triamterene or amiloride)
 - potassium supplements
 - salt substitutes that contain potassium
 - heparin - used to thin blood to prevent clot
 - cyclosporine, tacrolimus - medicines affecting the immune system
 - other medicines that may increase serum potassium (e.g., trimethoprim containing medicines)
- allopurinol, used to treat gout
- medicines used to treat diabetes. These include:
 - DPP-IV inhibitors, such as sitagliptin, linagliptin and saxagliptin
 - insulin
 - other oral antidiabetic medicines
- gold salts (sodium aurothiomalate) given by injection – used to treat arthritis
- baclofen, used to help relax certain muscles in the body
- estramustine, used to treat prostate cancer
- a class of medicine called nonsteroidal anti-inflammatory drugs (NSAIDs), used to reduce pain and swelling. Examples include aspirin, ibuprofen, naproxen, and celecoxib

- a class of medicine called vasodilators including nitrates (medicines such as nitroglycerin used to treat chest pain)
- digoxin, a medicine for the heart
- treatments where a machine removes blood from your body, filters it and returns the cleaned blood to your body (known as extracorporeal treatments). These include:
 - dialysis or haemofiltration, a process that removes wastes from your body in place of your kidneys using polyacrylonitrile membranes
 - low-density lipoprotein (LDL) apheresis, a treatment that removes the cholesterol from your blood using dextran sulphate
- gentamicin, an antibiotic
- medicines used to treat mood swings and other type of mental problems including schizophrenia, and depression. These include:
 - lithium
 - a class of medicine called tricyclic antidepressants such as amitriptyline, imipramine, nortriptyline
 - a class of medicine called antipsychotics such as clozapine, risperidone, pimozide, amisulpride, haloperidol
- anaesthetics, medicines to prevent pain during surgery
- medicines containing a neutral endopeptidase inhibitor (e.g., sacubitril), available in combination with valsartan, used to treat heart failure
- sirolimus, everolimus, temsirolimus and other drugs belonging to the class of medicines called mTOR inhibitors (used to avoid rejection of transplanted organs)
- certain medicines that you can buy without a prescription are known to cause your blood pressure to go up. These include medicines:
 - to control your hunger
 - for asthma
 - to treat colds and coughs
 - to treat allergies (such as hay fever)
 - to treat sinus problems

How to take COVERSYL:

- Take COVERSYL:
 - exactly as prescribed
 - about the same time every day preferably in the morning before a meal with a glass of water
- Swallow the tablet whole. You may break the 4 mg tablet as recommended by your healthcare professional.

Usual dose:

You and your healthcare professional will decide the best dose for you based on your needs.

Overdose:

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

Symptoms of an overdose include feeling light-headed or dizzy. This can happen because of a sudden or extreme drop in blood pressure.

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 COVERSYL?

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

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 (symptoms include a runny nose, sore throat)
- rash, itching
- headache, ringing in the ears
- stomach pain, loss of appetite, nausea, upset stomach, diarrhoea; changes in the sense of taste, dry mouth
- back pain
- loss of taste or metallic taste in your mouth
- muscle cramp or pain
- joint pain
- sleep problems (difficulty sleeping, feeling sleepy or drowsy)
- photosensitivity (sensitivity to sunlight): itchy, red skin when exposed to sunlight
- vision disturbance (double vision, blurred vision etc.)
- dry mouth
- fever
- excessive sweating
- falls
- tingling of the skin
- flushing

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	
COMMON			
Hyperkalemia (too much potassium in the blood): irregular heartbeat, muscle weakness and generally feeling unwell		✓	
Hypotension (low blood pressure): dizziness, fainting, light-headedness. May occur when you go from lying or sitting to standing up.	✓		
Persistent Cough		✓	

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	
UNCOMMON			
Angioedema and Severe Allergic Reaction: rash, hives, swelling of the face, hands and feet, genitals, lips, tongue or throat, difficulty swallowing or breathing, wheezing, swelling of the digestive tract causing stomach pain, diarrhea, nausea or vomiting			✓
Blood disorders: infections, fatigue, fever, aches, pains, and flu-like symptoms, bruising, bleeding, weakness, small purple or red dots under the skin		✓	
Cerebrovascular accident/Stroke (bleeding or blot clot in the brain): sudden numbness, weakness or tingling of the face, arm, or leg, particularly on one side of the body, sudden headache, blurred vision, difficulty swallowing or speaking, lethargy, dizziness, fainting, vomiting, trouble understanding, trouble with walking and loss of balance			✓
Chest pain		✓	
Depression (sad mood that won't go away): difficulty sleeping or sleeping too much, changes in appetite or weight, feelings of worthlessness, guilt, regret, helplessness or hopelessness, withdrawal from social situations, family, gatherings and activities with friends, reduced libido (sex drive) and thoughts of death or suicide		✓	
Edema (swelling of the hands, ankles or feet caused by too much fluid building up inside the body):	✓		

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	
swollen or puffy legs or hands, feeling heavy, achy or stiff			
Erectile Dysfunction: unable to get or keep an erection	✓		
Kidney problems: Change in frequency of urination, nausea, vomiting, swelling of extremities, fatigue		✓	
Myocardial Infarction (heart attack): pressure or squeezing pain between the shoulder blades, in the chest, jaw, left arm or upper abdomen, shortness of breath, dizziness, fatigue, light-headedness, clammy skin, sweating, indigestion, anxiety, feeling faint and possible irregular heartbeat			✓
Other Electrolyte Imbalance (too low or too high amounts of essential minerals like sodium, calcium, and potassium): weakness, drowsiness, muscle pain or cramps, irregular heartbeat		✓	
Palpitations (fast beating, fluttering or pounding heart): skipping beats, beating too fast, pounding, fluttering rapidly		✓	
Pemphigoid/Pemphigus: blisters of different sizes develop on the skin			✓
RARE			
Acute renal failure (severe kidney problems): confusion; itchiness or rashes; puffiness in your face and hands; swelling in your feet or ankles; urinating less or not at all; weight gain			✓
SIADH (syndrome of inappropriate antidiuretic hormone secretion): dark urine, nausea, vomiting,		✓	

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	
muscle cramps, confusion and fits (seizures)			
Worsening of psoriasis (chronic skin disease): red, itchy, scaly patches of the skin		✓	
VERY RARE			
Erythema multiforme (an allergic skin reaction): raised red or purple skin patches, possibly with blister or crust in the center; possibly swollen lips, mild itching or burning			✓
Liver problems: yellowing of the skin or eyes, dark urine, abdominal pain, nausea, vomiting, loss of appetite		✓	
Pancreatitis (inflammation of the Pancreas): upper abdominal pain, fever, rapid heart beat, nausea and vomiting, tenderness when touching the abdomen			✓
Steven-Johnson Syndrome (SJS), Toxic Epidermal Necrolysis (TEN) (severe skin reactions): any combination of itchy skin rash, redness, blistering and peeling of the skin and/or inside of the lips, eyes, mouth, nasal passages or genitals, accompanied by fever, chills, headache, cough, body aches or swollen glands, joint pain, yellowing of the skin or eyes, dark urine			✓
UNKNOWN			
Raynaud's phenomenon (episodes of reduced blood flow): cold feeling in fingers and toes (and sometimes nose, lips and ears), prickly or stinging feeling, change in skin colour to white then blue		✓	

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 (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.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:

- 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.

If you want more information about COVERSYL:

- 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>); the manufacturer's website (www.servier.ca), or by calling 1-800-363-6093.

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