

Patient Medication Information

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PrCOVERSYL® PLUS LD

PrCOVERSYL® PLUS

PrCOVERSYL® PLUS HD

perindopril erbumine / indapamide tablets

This Patient Medication Information is written for the person who will be taking **COVERSYL PLUS LD / COVERSYL PLUS / COVERSYL PLUS HD**. This may be you or a person you are caring for. Read this information carefully. Keep it as you may need to read it again.

This Patient Medication Information is a summary. It will not tell you everything about this medication. If you have more questions about this medication or want more information about **COVERSYL PLUS LD / COVERSYL PLUS / COVERSYL PLUS HD**, talk to a healthcare professional.

Serious warnings and precautions box

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

What COVERSYL PLUS LD / COVERSYL PLUS / COVERSYL PLUS HD is used for:

COVERSYL PLUS LD / COVERSYL PLUS / COVERSYL PLUS HD are used in adults (≥18 years of age) to treat mild to moderate High Blood Pressure.

How COVERSYL PLUS LD / COVERSYL PLUS / COVERSYL PLUS HD works:

COVERSYL PLUS LD / COVERSYL PLUS / COVERSYL PLUS HD contains 2 medicinal ingredients, perindopril and indapamide. They work together to control your blood pressure.

- Perindopril belongs to a class of medicines called angiotensin-converting enzyme (ACE) inhibitor. You can recognize ACE inhibitors because their medicinal ingredient ends in '-PRIL'. It works by relaxing the blood vessels so blood can flow more easily. This helps to lower blood pressure.
- Indapamide is in a class of medicines called diuretics ('water pills'). It works by causing the kidneys to get rid of unneeded water and salt from the body into the urine. This also helps to lower blood pressure.

This medicine does not cure high blood pressure. It helps to control it. Therefore, it is important to continue taking COVERSYL PLUS LD / COVERSYL PLUS / COVERSYL PLUS HD regularly even if you feel fine. Do not stop taking your medicine without the advice of your healthcare professional.

The ingredients in COVERSYL PLUS LD / COVERSYL PLUS / COVERSYL PLUS HD are:

Medicinal ingredients:

- Perindopril erbumine
- Indapamide

Non-medicinal ingredients:

- Hydrophobic colloidal silica
- Lactose monohydrate
- Magnesium stearate
- Microcrystalline cellulose

COVERSYL PLUS LD / COVERSYL PLUS / COVERSYL PLUS HD comes in the following dosage form(s):

- COVERSYL PLUS LD: tablets of 2 mg perindopril erbumine/ 0.625 mg indapamide.
- COVERSYL PLUS: tablets of 4 mg perindopril erbumine/ 1.25 mg indapamide.
- COVERSYL PLUS HD: tablets of 8 mg perindopril erbumine/ 2.5 mg indapamide.

Do not use COVERSYL PLUS LD / COVERSYL PLUS / COVERSYL PLUS HD if:

- are allergic to:
 - perindopril erbumine
 - indapamide or any medicines like indapamide (called sulphonamides)
 - any other non-medicinal ingredients in COVERSYL PLUS LD / COVERSYL PLUS / COVERSYL PLUS HD (see ingredients in COVERSYL PLUS LD / COVERSYL PLUS / COVERSYL PLUS HD are.)
- you ever had an allergic reaction (angioedema) involving swelling of the hands, feet, or ankles, face, lips, tongue, throat, or sudden difficulty breathing or swallowing:
 - to any other ACE inhibitor
 - where the reason is not known (idiopathic angioedema)
- you have been diagnosed with hereditary angioedema (an increased risk of getting an allergic reaction that is passed down through families).
- you are taking a medicine for heart failure containing sacubitril/ valsartan. Taking COVERSYL PLUS LD / COVERSYL PLUS / COVERSYL PLUS HD 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 PLUS LD / COVERSYL PLUS / COVERSYL PLUS HD.
- you are already taking a blood pressure-lowering medicine that contains aliskiren and you have diabetes or kidney disease.
- you have trouble urinating.
- you have severe liver disease or suffer from a condition called hepatic encephalopathy (a loss of brain function which occurs as a result of liver disease).
- you have low or high blood potassium.
- you suffer from a condition called decompensated heart failure (worsening of heart failure with symptoms such as shortness of breath, leg swelling).
- you are pregnant, planning on becoming pregnant or able to become pregnant and are not using a reliable birth control method. Taking COVERSYL PLUS LD / COVERSYL PLUS / COVERSYL PLUS HD during pregnancy can cause injury and even death to your baby. If you discover that

you are pregnant during treatment, stop taking COVERSYL PLUS LD / COVERSYL PLUS / COVERSYL PLUS HD and tell your healthcare professional right away.

- you are breast feeding or planning to breast feed. COVERSYL PLUS LD / COVERSYL PLUS / COVERSYL PLUS HD passes into breast milk.
- you are lactose intolerant or have one of the following rare hereditary diseases:
 - Galactose intolerance
 - Total lactase deficiency
 - Glucose-galactose malabsorption

Because COVERSYL PLUS LD / COVERSYL PLUS / COVERSYL PLUS HD contains lactose.

- you are taking medicines to treat heart rhythm problems.
- you are on dialysis or receive any other type of blood filtration. Depending on the machine that is used, COVERSYL PLUS LD / COVERSYL PLUS / COVERSYL PLUS HD may not be suitable for you.
- 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 PLUS LD / COVERSYL PLUS / COVERSYL PLUS HD. Talk about any health conditions or problems you may have, including if you:

- have a history of allergic reactions (angioedema).
- are of African origin. You may have a higher risk of experiencing serious allergic reactions (angioedema) while taking OVERSYL PLUS LD / COVERSYL PLUS / COVERSYL PLUS HD.
- have recently received or are planning to get allergy shots for bee or wasp stings.
- have any of the following health problems:
 - blood vessel problems
 - narrowing of the main blood vessel leading from the heart (aortic stenosis)
 - hardening of the arteries (atherosclerosis)
 - heart problems
 - heart muscle problems (hypertrophic cardiomyopathy)
 - heart rhythm problems
 - heart failure or any heart problems
 - have low blood pressure.
 - diabetes
 - have liver or kidney problems (including kidney transplantation).
 - have, or have had a condition, that causes a decrease in blood flow to your heart or brain (e.g., ischemic heart or cerebrovascular disease, angina, coronary artery disease, heart attack, stroke).
 - have an autoimmune disease such as systemic lupus erythematosus (SLE), an autoimmune disease that can affect many parts of the body and causes chronic inflammation to your skin, joints and/or blood vessels.
 - have been told by a healthcare professional that your blood is too acidic (metabolic acidosis).
 - 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).
 - a condition where your thyroid produce much hormones (hyperparathyroidism)
 - gout (a type of arthritis)
 - have muscle disorders including muscle pain, tenderness, weakness or cramps
- have had a heart attack or stroke.

- are taking any of the following medicines:
 - medicines used to lower blood pressure:
 - aliskiren
 - angiotensin receptor blockers (ARBs). You can recognize an ARB because its medicinal ingredient ends in "-SARTAN".
 - other ACE inhibitors.
 - certain anti-cancer medicines (e.g., 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
 - procainamide - used to treat irregular heartbeats
 - medicines containing a neutral endopeptidase inhibitor (e.g., sacubitril) to treat heart failure.
- 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 (sodium aurothiomalate) injections.
- are on LDL Apheresis (a treatment to lower the LDL cholesterol in the blood).
- are malnourished.
- are going to have surgery with anesthesia, including dental procedures.
- are 65 years of age or older. You may be more at risk of experiencing side effects.

Other warnings you should know about:

COVERSYL PLUS LD, COVERSYL PLUS or COVERSYL PLUS HD can cause serious side effects, including:

- **Allergic reaction and Angioedema:** Allergic reactions and angioedema (swelling of the face, lips, tongue, throat, digestive tract, genitals and/or difficulty breathing or swallowing) have happened in people taking COVERSYL PLUS LD, COVERSYL PLUS or COVERSYL PLUS HD. These side effects may happen at any time during treatment with COVERSYL PLUS LD, COVERSYL PLUS or COVERSYL PLUS HD, even if you have been taking it for a long period without problems. Very rarely, cases have been fatal. If you experience symptoms of an allergic reaction or angioedema, stop taking COVERSYL PLUS LD, COVERSYL PLUS or COVERSYL PLUS HD 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 PLUS LD, COVERSYL PLUS or COVERSYL PLUS HD 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 PLUS LD, COVERSYL PLUS or COVERSYL PLUS HD and talk to your healthcare professional.

- **Blood disorders:** ACE inhibitors, such as COVERSYL PLUS LD, COVERSYL PLUS or COVERSYL PLUS HD, may cause:
 - neutropenia / Agranulocytosis (decrease in white blood cells)
 - thrombocytopenia (low blood platelets)
 - anemia (low red blood cells)
- **Hypoglycemia (low blood sugar):** COVERSYL PLUS LD, COVERSYL PLUS or COVERSYL PLUS HD 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 PLUS LD, COVERSYL PLUS or COVERSYL PLUS HD.

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

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

Eye Problems: COVERSYL PLUS LD, COVERSYL PLUS or COVERSYL PLUS HD may cause sudden eye problems with changes in your vision or pain in one or both of your eyes such as:

- myopia or nearsightedness: trouble seeing things that are far away
- glaucoma: a disease that damages your eye's nerve. It usually happens when liquid builds up and increases pressure inside the eye. Untreated, it may lead to blindness
- choroidal effusion: an abnormal building of liquid in your eye that may result in vision changes.

These eye problems may happen within hours to weeks of starting COVERSYL PLUS LD, COVERSYL PLUS or COVERSYL PLUS HD. If you experience any of the above symptoms, stop taking COVERSYL PLUS LD, COVERSYL PLUS or COVERSYL PLUS HD and seek immediate medical help

Athletes: COVERSYL PLUS LD, COVERSYL PLUS or COVERSYL PLUS HD contains a medicinal ingredient (indapamide) which may give a positive reaction in doping tests.

Increased sensitivity of the skin to sun: Your skin may become sensitive to the sun while taking COVERSYL PLUS LD, COVERSYL PLUS or COVERSYL PLUS HD. 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 PLUS LD, COVERSYL PLUS or COVERSYL PLUS HD. You may experience a sudden fall in blood pressure when you are under general anesthesia. Your healthcare professional may ask you to stop taking COVERSYL PLUS LD, COVERSYL PLUS or COVERSYL PLUS HD one day before your surgery. Follow their instructions exactly.

Testing and check-ups: Your healthcare professional may do tests, including blood tests, before you

take COVERSYL PLUS LD, COVERSYL PLUS or COVERSYL PLUS HD and/or during treatment. These tests will check:

- your blood pressure
- the level of red and white blood cells and platelets in your body
- that your liver or kidneys are working properly.
- the potassium and sodium 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 PLUS LD, COVERSYL PLUS or COVERSYL PLUS HD. 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 PLUS LD / COVERSYL PLUS / COVERSYL PLUS HD:

- medicines that lower your blood pressure. These include:
 - diuretics (“water pills”)
 - aliskiren-containing medicines
 - angiotensin Receptor Blockers (ARBs)
 - other ACE inhibitors
 - calcium channel blockers (e.g., verapamil, diltiazem)
- 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 and prevent blood clots
 - cyclosporine, tacrolimus and sirolimus - medicines affecting the immune system
 - other medicines that may increase serum potassium (e.g., trimethoprim containing medicines)
- digoxin (a heart medication)
- medicines used to treat diabetes. These include:
 - a class of medicine called (dipeptidyl peptidase IV DPP-IV inhibitors). You can recognize a DPP-IV inhibitor because its medicinal ingredient ends in “-GLIPTIN”, such as sitagliptin, linagliptin and saxagliptin
 - Insulin
 - metformin or other antidiabetic medicines taken by mouth
- a class of medicine called non-steroidal anti-inflammatory medicines (NSAIDs), used to reduce pain, fever and inflammation such as ibuprofen, naproxen, or celecoxib or high doses of acetylsalicylic acid (more than 3 g/day);
- a class of medicine called vasodilators including nitrates (medicines such as nitroglycerin used to treat chest pain)
- 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, donepezil
- a class of medicine called serotonin reuptake inhibitors (SSRIs eg. paroxetine, sertraline, citalopram, escitalopram)
- medicines that suppress the immune system, such as ciclosporin, tacrolimus
- gold salts (sodium aurothiomalate) given by injection – used to treat arthritis
- clofibrate - medicine used to help lower high a type of fat in your blood
- medicines to treat heart rhythm problems (e.g. digoxine, quinidine, hydroquinidine, disopyramide, amiodarone, sotalol, ibutilide, dofetilide, procainamide, flecainide)
- allopurinol, used to treat gout
- oral corticosteroids for treatment of asthma
- medicines for the treatment of cancer (e.g. vandetanib, oxaliplatin)
- baclofen, used to help relax certain muscles in the body
- calcium tablets or other calcium supplements
- anaesthetic, medicines to prevent pain during surgery (e.g. propofol, sevoflurane);
- iodinated contrast media – used for X-Ray
- stimulant laxatives such as bisacodyl and senna
- antifungal medications such as amphotericin B (IV), fluconazole
- tetracosactide used to treat 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
- pentamidine (used to treat pneumonia)
- antibiotics used to treat bacterial infections (e.g., moxifloxacin, erythromycin IV, gentamycin, ciprofloxacin, clarithromycin)
- estramustine (used in cancer therapy)
- 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
- medicines containing a neutral endopeptidase (NEP) inhibitor (e.g., sacubitril), available in combination with valsartan, used to treat heart failure. The combination with COVERSYL PLUS LD, COVERSYL PLUS or COVERSYL PLUS HD is not recommended
- sirolimus, everolimus, temsirolimus and other medicines belonging to the class of mTOR inhibitors (used to avoid rejection of transplanted organs and to treat certain types of cancer)
- anagrelide (used to reduce the number of platelets (a type of blood cell that is needed to control bleeding))
- medicines used to treat nausea and vomiting (e.g. ondansetron, domperidone)
- methadone (used to treat addiction or relieve severe pain)
- medicines used to prevent and treat malaria. e.g. chloroquine)
- papaverine (a medicine used to relax muscles in your blood vessels thereby increasing blood flow)
- 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 PLUS LD / COVERSYL PLUS / COVERSYL PLUS HD:

- Take COVERSYL PLUS LD, COVERSYL PLUS or COVERSYL PLUS HD
 - exactly as prescribed.
 - once daily at the same time every day, preferably **in the morning** before a meal with a glass of water.
 - Swallow the tablet whole.

Usual dose:

Your healthcare professional will decide on the dose that is right for you based on your needs. If you have kidney problems, you and your healthcare professional will decide the best dose for you based on your needs.

Overdose:

Symptoms of an overdose with COVERSYL PLUS LD, COVERSYL PLUS, COVERSYL PLUS HD may include:

- low blood pressure
- nausea and vomiting
- cramps
- dizziness
- sleepiness
- mental confusion
- peeing a lot more than normal, a lot less than normal or not at all.

If you think you, or a person you are caring for, have taken too much COVERSYL PLUS LD, COVERSYL PLUS, COVERSYL PLUS HD, contact a healthcare professional, hospital emergency department, regional poison control centre or Health Canada's toll-free number, 1-844 POISON-X (1-844-764-7669) immediately, even if there are no signs or symptoms.

Missed dose:

If you miss a dose of your medication, skip your missed dose and take the next dose at your usual scheduled time. Do not double your dose to make up for a missed dose.

Possible side effects from using COVERSYL PLUS LD / COVERSYL PLUS / COVERSYL PLUS HD:

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

Side effects may include:

- dizziness, drowsiness, fatigue, weakness, headache, vertigo, malaise, falls
- sensitivity to light
- rash, itching, redness of the skin

- stomach problems including pain in the stomach area, indigestion, loss of appetite, nausea, vomiting constipation, diarrhoea; changes in the sense of taste, dry mouth
- cough (often described as dry and irritating, usually is worse at night or when lying down)
- common cold symptoms (sore throat, fever)
- sleep problems
- sweating
- muscle cramps and/or pain, joint pain or swelling
- flushing
- weight loss
- tingling of the skin “pins and needles” sensation of the skin

Serious side effects and what to do about them

Frequency/Side Effect/Symptom	Talk to your healthcare professional		Stop taking this drug and get immediate medical help
	Only if severe	In all cases	
Common			
Hypokalemia (low level of potassium in the blood): muscle weakness, muscle spasms, cramping, constipation, feeling of skipped heart beats or palpitations, fatigue, tingling or numbness		✓	
Hypotension (low blood pressure): dizziness, fainting, light-headedness. May occur when you go from lying or sitting to standing up	✓		
Persistent cough		✓	
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			✓
Bronchospasm: difficulty breathing and coughing, chest tightness, wheezing or whistling sound when breathing			✓
Depression (sad mood that won't go away): difficulty sleeping or sleeping too much, changes in appetite or weight, feelings of worthlessness, guilt, regret.		✓	

Frequency/Side Effect/Symptom	Talk to your healthcare professional		Stop taking this drug and get immediate medical help
	Only if severe	In all cases	
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): swollen or puffy legs or hands, feeling heavy, achy or stiff	✓		
Erectile dysfunction: unable to get or keep an erection	✓		
Hyperkalemia (too much potassium in the Blood): irregular heartbeat, muscle weakness and generally feeling unwell		✓	
Hyponatremia (Low sodium in the Blood) that may lead to: - dehydration (happens when your body doesn't have as much water as it needs; leading to extreme thirst), - low blood pressure: blurred vision, dizziness, light-headedness, fainting		✓	
Kidney problems: change in frequency of urination, nausea, vomiting, swelling of extremities, fatigue		✓	
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			✓
Worsening angina (chest pain): discomfort in the shoulder, arm, back, throat, jaw or teeth, pain or pressure in the chest		✓	
Rare			
Acute renal failure (severe kidney problems): confusion, itchiness or			✓

Frequency/Side Effect/Symptom	Talk to your healthcare professional		Stop taking this drug and get immediate medical help
	Only if severe	In all cases	
rashes, puffiness in your face and hands, swelling in your feet or ankles, urinating less or not at all, weight gain			
Hypochloremia (low chloride in the Blood): diarrhea, unusual tiredness or weakness, dehydration		✓	
Hypomagnesaemia (low magnesium in the Blood): shaking, unusual tiredness or weakness, muscle cramps, numbness, eye movements problems, seizures.		✓	
SIADH (syndrome of inappropriate antidiuretic hormone secretion): dark urine, nausea, vomiting, muscle cramps, confusion and fits (seizures)		✓	
Worsening of Psoriasis (chronic skin disease): red, itchy, scaly patches of the skin		✓	
Very rare			
Blood disorders: infections, fatigue, fever, aches, pains, and flu-like symptoms, bruising, bleeding, fatigue and weakness, small purple or red dots under the skin.		✓	
Cerebrovascular accident/Stroke (bleeding or blood clot in the brain): sudden numbness, weakness or tingling of the face, arm, or leg, particularly on one side of the body, sudden headache, blurry vision, difficulty swallowing or speaking, or lethargy, dizziness, fainting, vomiting, trouble understanding, trouble with walking and loss of balance			✓
Erythema multiforme (an allergic skin reaction): raised red or purple skin patches, possibly with blister or crust in the center; possibly			✓

Frequency/Side Effect/Symptom	Talk to your healthcare professional		Stop taking this drug and get immediate medical help
	Only if severe	In all cases	
swollen lips, mild itching or burning.			
Liver Problems: yellowing of the skin or eyes, dark urine, abdominal pain, nausea, vomiting, loss of appetite		✓	
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			✓
Pancreatitis (inflammation of the pancreas): upper abdominal pain, fever, rapid heartbeat, nausea and vomiting, tenderness when touching the abdomen			✓
Stevens-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			
Arrhythmia (abnormal heart rhythms): rapid, slow or irregular heartbeat		✓	
Eye problems: - Myopia (near sightedness): blurred vision, difficulty focusing on objects far away, need to squint, headache caused by eyestrain, fatigue			✓

Frequency/Side Effect/Symptom	Talk to your healthcare professional		Stop taking this drug and get immediate medical help
	Only if severe	In all cases	
- Glaucoma: blurred vision, halos around lights, eye pain and redness, nausea and vomiting, severe headache			
Hyperglycemia (high blood sugar): increased thirst, frequent urination, dry skin, headache, blurred vision and fatigue	✓		
Increased Levels of Uric Acid in the Blood: swelling and redness in the joints		✓	
Possible worsening of pre-existing lupus (an autoimmune disease that occurs when your body's immune system attacks your own tissues and organs, including your joints, skin, kidneys, blood cells, heart and lungs): fatigue, fever, joint pain, stiffness and swelling, rash on the face that covers the cheeks and the bridge of the nose or rashes elsewhere on the body, skin lesions, shortness of breath, chest pain, dry eyes, headaches, confusion and memory loss			✓
Raynaud's phenomenon (episodes of reduced blood flow): cold feeling in fingers or toes (and sometimes nose, lips and ears), prickly or stinging feeling, change in skin colour to white then blue		✓	
Rhabdomyolysis (breakdown of damaged muscle): muscle pain that you cannot explain, muscle tenderness or weakness, red-brown (tea-coloured) urine		✓	
Torsade de pointes: life-threatening irregular heartbeat			✓

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 (canada.ca/drug-device-reporting) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your healthcare 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.
- COVERSYL PLUS LD, COVERSYL PLUS and COVERSYL PLUS HD: store at room temperature (15°C - 30°C).
- COVERSYL PLUS and COVERSYL PLUS HD bottles: 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 PLUS LD / COVERSYL PLUS / COVERSYL PLUS HD:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes the Patient Medication Information by visiting the Health Canada Drug Product Database website (<https://health-products.canada.ca/dpd-bdpp/>); the manufacturer's website (www.servier.ca); or by calling 1-800-363-6093.

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