

PART III: CONSUMER INFORMATION

Pr **COVERSYL® PLUS LD**
Pr **COVERSYL® PLUS**
Pr **COVERSYL® PLUS HD**

perindopril erbumine/ indapamide tablets

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

ABOUT THIS MEDICATION

What the medication is used for:

COVERSYL® PLUS LD/ COVERSYL® PLUS/ COVERSYL® PLUS HD are combinations of two active ingredients, perindopril and indapamide used to treat mild to moderate **High Blood Pressure**.

What it does:

Perindopril is an angiotensin converting enzyme (ACE) inhibitor. You can recognize ACE inhibitors because their medicinal ingredient ends in ‘-PRIL’.

Indapamide is a diuretic often called a “water pill”. It increases urination. This lowers blood pressure. Indapamide affects the kidney’s ability to reabsorb electrolytes.

Each of the active ingredients reduces blood pressure and they work together to control your blood pressure.

High blood pressure increases the workload of the heart and arteries. If this condition continues for a long time, damage to the blood vessels of the brain, heart, and kidneys can occur, and may eventually result in a stroke, heart or kidney failure. High blood pressure also increases the risk of heart attacks. Reducing your blood pressure decreases your risk of developing these illnesses.

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 doctor.

When it should not be used:

Do not take COVERSYL® PLUS LD/ COVERSYL® PLUS/ COVERSYL® PLUS HD if you:

- are allergic to perindopril erbumine or any other ACE inhibitor, or to indapamide or any other sulphonamides, or to any other

- non-medicinal ingredients of COVERSYL® PLUS LD/ COVERSYL® PLUS/ COVERSYL® PLUS HD
 - previously 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.
 - 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 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® PLUS LD/ COVERSYL® PLUS/ COVERSYL® PLUS HD
 - are already taking a blood pressure-lowering medicine that contains aliskiren (such as RASILEZ) and you have diabetes or kidney disease.
 - have trouble urinating,
 - have severe liver disease or suffer from a condition called hepatic encephalopathy (a degenerative disease of the brain),
 - have a kidney disease,
 - have low or high blood potassium,
 - are suspected of having untreated decompensated heart failure (severe water retention, difficulty in breathing),
 - are pregnant or intend to become pregnant. Taking of COVERSYL® PLUS LD/ COVERSYL® PLUS/ COVERSYL® PLUS HD during pregnancy can cause injury and even death to your baby.
 - are breast feeding. COVERSYL® PLUS LD/ COVERSYL® PLUS/ COVERSYL® PLUS HD 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® PLUS LD/ COVERSYL® PLUS/ COVERSYL® PLUS HD.
- are taking drugs to treat heart rhythm disturbances (antiarrhythmics) that might cause severe cardiac arrhythmias
 - are on dialysis or 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.
 - have kidney problems where the blood supply to your kidneys is significantly reduced (renal artery stenosis).

What the medicinal ingredients are:

Perindopril erbumine and indapamide.

What the nonmedicinal ingredients are:

Hydrophobic colloidal silica, lactose monohydrate, magnesium stearate, and microcrystalline cellulose.

What dosage forms it comes in:

- 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.

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions - Pregnancy

COVERSYL® PLUS LD/ COVERSYL® PLUS/ COVERSYL® PLUS HD should not be used during pregnancy. If you discover that you are pregnant while taking COVERSYL® PLUS LD, COVERSYL® PLUS or COVERSYL® PLUS HD, stop the medication and contact your doctor, nurse, or pharmacist as soon as possible.

BEFORE you use COVERSYL® PLUS LD/ COVERSYL® PLUS/ COVERSYL® PLUS HD talk to your doctor 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 aortic stenosis (narrowing of the main blood vessel leading from the heart) or hypertrophic cardiomyopathy (cardiac muscle disease) or renal artery stenosis (narrowing of the artery supplying the kidney with blood),
- have/had a heart attack or a stroke,
- have diabetes, liver or kidney disease,
- are taking a medicine that contains aliskiren, such as RASILEZ, used to lower high blood pressure. The combination with COVERSYL® PLUS LD/ COVERSYL® PLUS/ COVERSYL® PLUS HD is not recommended.
- are taking an angiotensin receptor blocker (ARB). You can recognize an ARB because its medicinal ingredient ends in "-SARTAN",
- are on haemodialysis,
- have a history of angioedema (swelling around your face, throat or tongue),
- suffer from a collagen disease (skin disease) such as systemic lupus erythematosus or scleroderma,
- have atherosclerosis (hardening of the arteries),
- suffer from hyperparathyroidism (dysfunctioning of the parathyroid gland),
- suffer from gout,
- are on a salt restricted diet or use salt substitutes which contain potassium, potassium supplements, or a potassium-sparing diuretic (a specific kind of "water pill"),
- take lithium or potassium-sparing diuretics (spironolactone, triamterene) as their use with COVERSYL® PLUS LD, COVERSYL® PLUS or COVERSYL® PLUS HD should be avoided.

- are dehydrated or have recently suffered from excessive vomiting or diarrhea, or sweating,
- are receiving gold (sodium aurothiomalate) injections,
- are on LDL Apheresis (a treatment to lower the LDL cholesterol in the blood),
- have any congenital or a family history of heart rhythm problems,
- are less than 18 years old,
- are malnourished,
- are over 65 years old,
- have any other heart problems,
- are to undergo anesthesia and/or surgery.
- have abnormally increased levels of a hormone called aldosterone in your blood (primary aldosteronism).

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

Athletes should be aware that COVERSYL® PLUS LD, COVERSYL® PLUS or COVERSYL® PLUS HD contains a medicinal ingredient (indapamide) which may give a positive reaction in doping tests.

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

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, 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® PLUS LD/ COVERSYL® PLUS/ COVERSYL® PLUS HD:

- lithium (used to treat bipolar disorder),
- agents affecting sympathetic activity,
- agents causing renin release,
- blood pressure-lowering drugs, including diuretics (“water pills”), aliskiren-containing products (e.g. RASILEZ), or angiotensin receptor blockers (ARBs),
- 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”),
- digoxin (a heart medication),
- medicines to treat diabetes such as insulin, gliptins or metformin,
- non-steroidal anti-inflammatory drugs (NSAIDs), such as ibuprofen, naproxen, or celecoxib or high doses of acetylsalicylic acid (more than 3 g/day),
- drugs used to treat anxiety and schizophrenia (e.g. clozapine, risperidone, pimozide),
- drugs used to treat depression, in particular serotonin reuptake inhibitors (SSRIs eg. paroxetine, sertraline, citalopram) and tricyclic antidepressants (imipramine),
- gold for the treatment of rheumatoid arthritis
- drugs to treat heart rhythm disturbances (e.g. digoxine, quinidine, hydroquinidine, disopyramide, amiodarone, sotalol, ibutilide, dofetilide, procainamide),
- allopurinol (for the treatment of gout),
- oral corticosteroids for treatment of asthma,
- ciclosporin, tacrolimus or other medications to depress the immune system after organ transplantation,
- medicines for the treatment of cancer,
- baclofen, a skeletal muscle relaxant,
- calcium tablets or other calcium supplements,
- anaesthetics,
- iodinated contrast media,
- stimulant laxatives such as bisacodyl and senna,
- antifungal medications such as amphotericin B (IV),
- 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,
- antimicrobial medications such as pentamidine.
- Antibiotics such as moxifloxacin, erythromycin IV, gentamycin,
- Trimethoprim (for the treatment of infections),
- Estramustine (used in cancer therapy)
- Neutral endopeptidase (NEP) inhibitors. The combination with COVERSYL® PLUS LD, COVERSYL® PLUS or

COVERSYL® PLUS HD 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® PLUS LD, COVERSYL® PLUS or COVERSYL® PLUS HD exactly as prescribed. It is recommended to take your dose at about the same time every day. Swallow the table whole with water.

Usual Adult dose:

The recommended dose of COVERSYL® PLUS LD, COVERSYL® PLUS, COVERSYL® PLUS HD is one tablet once daily taken in the morning before a meal. Your doctor may decide to modify the dosage regimen in particular if you suffer from renal impairment.

Overdose:

If you think you have taken too much COVERSYL® PLUS LD/ COVERSYL® PLUS/ COVERSYL® PLUS HD, 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, headache, vertigo, malaise, fall
- rash, itching
- gastro-intestinal disorders, stomach or abdominal pain, loss of appetite, nausea, vomiting, constipation, diarrhea
- taste disturbance
- dry mouth, dry cough
- mood swings, sleep disturbances
- sweating
- muscle cramps and/or pain, joint pain, pins and needles sensation

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

If you faint, discontinue the drug and contact your doctor.

COVERSYL® PLUS LD, COVERSYL® PLUS or COVERSYL® PLUS HD 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 or pharmacist		Stop taking drug and seek immediate medical help
		Only if severe	In all cases	
Uncommon	Possible worsening of pre-existing lupus: a disease affecting the skin, joints and kidney			✓
	Low blood pressure: dizziness, fainting, lightheadedness. May occur when you go from lying or sitting to standing up.	✓		
	Angioedema and Severe Allergic Reaction: swelling of the face, eyes or tongue, difficulty swallowing, wheezing, difficulty breathing, abdominal cramps, chest discomfort or tightness, hives and generalized itching, rash, fever, unconsciousness*			✓
	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.		✓	
	Fast or irregular heartbeat		✓	

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM				
Symptom / Effect		Talk with your doctor or pharmacist		Stop taking drug and seek immediate medical help
		Only if severe	In all cases	
Uncommon	Bronchospasm (difficulty in breathing)			✓
	Chest pain		✓	
	Edema: swelling of the legs, feet and ankles	✓		
	Pemphigoid/ Pemphigus: formation of blister clusters over the skin			✓
Rare	Increased Levels of Calcium in the Blood: loss of appetite, nausea, vomiting, constipation, stomach pain.		✓	
	Psoriasis Aggravation		✓	
Very rare	Anemia: fatigue, loss of energy, weakness, shortness of breath		✓	
	Decreased White Blood Cells: infections, fatigue, fever, aches, pains and flu-like symptoms		✓	
	Decreased Platelets: bruising, bleeding, fatigue, weakness		✓	
	Inflammation of the pancreas: abdominal pain that lasts and gets worse when you lie down, nausea, vomiting		✓	

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM			
Symptom / Effect	Talk with your doctor or pharmacist		Stop taking drug and seek immediate medical help
	Only if severe	In all cases	
Severe skin reactions (Stevens-Johnson Syndrome, Toxic Epidermal Necrolysis, Hypersensitivity Syndrome): 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.			✓
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)		✓	
Unknown Torsade de pointes: life-threatening irregular heartbeat			✓

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM			
Symptom / Effect	Talk with your doctor or pharmacist		Stop taking drug and seek immediate medical help
	Only if severe	In all cases	
Increased Blood Sugar: frequent urination, thirst, hunger	✓		
Increased Levels of Potassium in the Blood: irregular heartbeat, muscle weakness and generally feeling unwell		✓	
Increased Levels of Uric Acid in the Blood: swelling and redness in the joints		✓	
Eye Disorders: -Myopia: sudden near sightedness or blurred vision.			✓
Rhabdomyolysis: muscle pain that you cannot explain, muscle tenderness or weakness, dark brown urine.		✓	
Electrolyte Imbalance: weakness, drowsiness, muscle pain or cramps, irregular heartbeat		✓	

* This is known to occur more frequently in black patients.

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

HOW TO STORE IT

Keep out of reach or sight of children.

For COVERSYL® PLUS LD, COVERSYL® PLUS (4 mg/1.25 mg) and COVERSYL® PLUS HD store at room temperature (15°C-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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