

## PATIENT MEDICATION INFORMATION

### READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

**Pr**PERINDOPRIL ERBUMINE / INDAPAMIDE

**Pr**PERINDOPRIL ERBUMINE / INDAPAMIDE HD

**perindopril erbumine / indapamide tablets**

Read this carefully before you start taking **PERINDOPRIL ERBUMINE / INDAPAMIDE** or **PERINDOPRIL ERBUMINE / INDAPAMIDE HD** 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 **PERINDOPRIL ERBUMINE / INDAPAMIDE** and **PERINDOPRIL ERBUMINE / INDAPAMIDE HD**.

#### Serious Warnings and Precautions

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

#### What is PERINDOPRIL ERBUMINE / INDAPAMIDE and PERINDOPRIL ERBUMINE / INDAPAMIDE HD used for?

PERINDOPRIL ERBUMINE / INDAPAMIDE and PERINDOPRIL ERBUMINE / INDAPAMIDE HD are used in adults to treat mild to moderate **High Blood Pressure**.

#### How does PERINDOPRIL ERBUMINE / INDAPAMIDE and PERINDOPRIL ERBUMINE / INDAPAMIDE HD work?

PERINDOPRIL ERBUMINE / INDAPAMIDE and PERINDOPRIL ERBUMINE / INDAPAMIDE HD contains 2 medicines, 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 PERINDOPRIL ERBUMINE / INDAPAMIDE and PERINDOPRIL ERBUMINE / INDAPAMIDE HD regularly even if you feel fine. Do not stop taking your medicine without the advice of your healthcare professional.

**What are the ingredients in PERINDOPRIL ERBUMINE / INDAPAMIDE and PERINDOPRIL ERBUMINE / INDAPAMIDE HD?**

Medicinal ingredients: perindopril erbumine and indapamide

Non-medicinal ingredients: hydrophobic colloidal silica, lactose monohydrate, magnesium stearate and microcrystalline cellulose

**PERINDOPRIL ERBUMINE / INDAPAMIDE and PERINDOPRIL ERBUMINE / INDAPAMIDE HD comes in the following dosage forms:**

- PERINDOPRIL ERBUMINE / INDAPAMIDE: tablets of 4 mg perindopril erbumine/ 1.25 mg indapamide.
- PERINDOPRIL ERBUMINE / INDAPAMIDE HD: tablets of 8 mg perindopril erbumine/ 2.5 mg indapamide.

**Do not use PERINDOPRIL ERBUMINE / INDAPAMIDE and PERINDOPRIL ERBUMINE / INDAPAMIDE HD if you:**

- are allergic to:
  - perindopril erbumine
  - indapamide or any medicines like indapamide (called sulphonamides)
  - to any other non-medicinal ingredients in PERINDOPRIL ERBUMINE / INDAPAMIDE<sub>7</sub> and PERINDOPRIL ERBUMINE / INDAPAMIDE HD (see What are the ingredients in PERINDOPRIL ERBUMINE / INDAPAMIDE<sub>7</sub> and PERINDOPRIL ERBUMINE / INDAPAMIDE HD?)
- have had an allergic reaction (angioedema) with 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)
- have been diagnosed with hereditary angioedema (an increased risk of getting an allergic reaction that is passed down through families)
- are taking a medicine for heart failure containing sacubitril/ valsartan. Taking PERINDOPRIL ERBUMINE / INDAPAMIDE or PERINDOPRIL ERBUMINE / INDAPAMIDE 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 PERINDOPRIL ERBUMINE / INDAPAMIDE or PERINDOPRIL ERBUMINE / INDAPAMIDE HD
- are already taking a blood pressure-lowering medicine that contains aliskiren and you have diabetes or kidney disease
- have trouble urinating
- 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)
- have low or high blood potassium
- suffer from a condition called decompensated heart failure (worsening of heart failure with symptoms such as shortness of breath, leg swelling)

- are pregnant or planning to become pregnant. Taking PERINDOPRIL ERBUMINE / INDAPAMIDE or PERINDOPRIL ERBUMINE / INDAPAMIDE HD during pregnancy can cause injury and even death to your baby
- are breast feeding. PERINDOPRIL ERBUMINE / INDAPAMIDE and PERINDOPRIL ERBUMINE / INDAPAMIDE HD passes into breast milk
- are lactose intolerant or have one of the following rare hereditary diseases:
  - Galactose intolerance
  - Total lactase deficiency
  - Glucose-galactose malabsorption
 Because lactose is a non-medicinal ingredient in PERINDOPRIL ERBUMINE / INDAPAMIDE and PERINDOPRIL ERBUMINE / INDAPAMIDE HD.
- are taking medicines to treat heart rhythm problems
- are on dialysis or receive any other type of blood filtration. Depending on the machine that is used, PERINDOPRIL ERBUMINE / INDAPAMIDE and PERINDOPRIL ERBUMINE / INDAPAMIDE HD 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 PERINDOPRIL ERBUMINE / INDAPAMIDE or PERINDOPRIL ERBUMINE / INDAPAMIDE 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
- 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
  - low blood pressure
  - diabetes, liver or kidney problems
  - 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)
  - 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 blocker (ARB). You can recognize an ARB because its medicinal ingredient ends in "-SARTAN";
- 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
  - 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 65 years of age or older. You may be more at risk of experiencing side effects

**Other warnings you should know about:**

PERINDOPRIL ERBUMINE / INDAPAMIDE or PERINDOPRIL ERBUMINE / INDAPAMIDE HD 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 PERINDOPRIL ERBUMINE / INDAPAMIDE or PERINDOPRIL ERBUMINE / INDAPAMIDE HD. 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 PERINDOPRIL ERBUMINE / INDAPAMIDE or PERINDOPRIL ERBUMINE / INDAPAMIDE 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 PERINDOPRIL ERBUMINE / INDAPAMIDE or PERINDOPRIL ERBUMINE / INDAPAMIDE 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 PERINDOPRIL ERBUMINE / INDAPAMIDE or PERINDOPRIL ERBUMINE / INDAPAMIDE HD and talk to your healthcare professional.

**Blood disorders:** ACE inhibitors, such as PERINDOPRIL ERBUMINE / INDAPAMIDE or PERINDOPRIL ERBUMINE / INDAPAMIDE HD, may cause:

- neutropenia / agranulocytosis (decrease in white blood cells)
- thrombocytopenia (low blood platelets)
- anaemia (low red blood cells)
- **Hypoglycemia (low blood sugar):** PERINDOPRIL ERBUMINE / INDAPAMIDE or PERINDOPRIL ERBUMINE / INDAPAMIDE 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 PERINDOPRIL ERBUMINE / INDAPAMIDE or PERINDOPRIL ERBUMINE / INDAPAMIDE HD.

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 PERINDOPRIL ERBUMINE / INDAPAMIDE or PERINDOPRIL ERBUMINE / INDAPAMIDE HD. This usually goes away once you stop taking PERINDOPRIL ERBUMINE / INDAPAMIDE or PERINDOPRIL ERBUMINE / INDAPAMIDE HD or when the dose is lowered. Tell your healthcare professional if you experience this symptom.

**Eye Problems:** PERINDOPRIL ERBUMINE / INDAPAMIDE or PERINDOPRIL ERBUMINE / INDAPAMIDE 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 PERINDOPRIL ERBUMINE / INDAPAMIDE or PERINDOPRIL ERBUMINE / INDAPAMIDE HD. If you experience any of the above symptoms, stop taking PERINDOPRIL ERBUMINE / INDAPAMIDE or PERINDOPRIL ERBUMINE / INDAPAMIDE HD and seek immediate medical help

**Athletes:** PERINDOPRIL ERBUMINE / INDAPAMIDE or PERINDOPRIL ERBUMINE / INDAPAMIDE 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 PERINDOPRIL ERBUMINE / INDAPAMIDE or PERINDOPRIL ERBUMINE / INDAPAMIDE 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 PERINDOPRIL ERBUMINE / INDAPAMIDE or PERINDOPRIL ERBUMINE / INDAPAMIDE HD. 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 PERINDOPRIL ERBUMINE / INDAPAMIDE or PERINDOPRIL ERBUMINE / INDAPAMIDE HD 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 PERINDOPRIL ERBUMINE / INDAPAMIDE or PERINDOPRIL ERBUMINE / INDAPAMIDE 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 PERINDOPRIL ERBUMINE / INDAPAMIDE and PERINDOPRIL ERBUMINE / INDAPAMIDE HD:**

- medicines that lower your blood pressure. These include:
  - diuretics (“water pills”)
  - aliskiren-containing medicines
  - Angiotensin Receptor Blockers (ARBs)
- 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)
- digoxin (a heart medication)
- medicines used to treat diabetes. These include:
  - a class of medicine called DPP-IV inhibitors 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), 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)
- 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 such as 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 inhibitor (e.g., sacubitril), available in combination with valsartan, used to treat heart failure. The combination with PERINDOPRIL ERBUMINE / INDAPAMIDE or PERINDOPRIL ERBUMINE / INDAPAMIDE HD is not recommended
- sirolimus, everolimus, temsirolimus and other medicines belonging to the class of mTOR inhibitors (used to avoid rejection of transplanted organs)
- 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 PERINDOPRIL ERBUMINE / INDAPAMIDE and PERINDOPRIL ERBUMINE / INDAPAMIDE HD:**

- Take PERINDOPRIL ERBUMINE / INDAPAMIDE or PERINDOPRIL ERBUMINE / INDAPAMIDE HD
  - 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.

### **Usual adult dose:**

Take one tablet once daily taken in the morning before a meal.

If you have kidney problems, 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 PERINDOPRIL ERBUMINE / INDAPAMIDE or PERINDOPRIL ERBUMINE / INDAPAMIDE HD, contact a healthcare professional, 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.

### **What are possible side effects from using PERINDOPRIL ERBUMINE / INDAPAMIDE or PERINDOPRIL ERBUMINE / INDAPAMIDE HD?**

These are not all the possible side effects you may have when taking PERINDOPRIL ERBUMINE / INDAPAMIDE or PERINDOPRIL ERBUMINE / INDAPAMIDE 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, fall
- rash, itching
- stomach problems including pain in the stomach area, 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)
- sleep problems
- sweating
- muscle cramps and/or pain, joint pain, pins and needles sensation
- flushing
- tingling of the skin



| 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 |   |
| <b>COMMON</b>  |                                      |              |   |
| <b>Hypokalemia</b> (low level of potassium in the blood): muscle weakness, muscle spasms, cramping, constipation, feeling of skipped heart beats or palpitations, fatigue, tingling or numbness  |                                      | ✓            |   |
| <b>Hypotension</b> (low blood pressure): dizziness, fainting, light-headedness. May occur when you go from lying or sitting to standing up   | ✓                                    |              |   |
| <b>Persistent cough</b>  |                                      | ✓            |   |
| <b>UNCOMMON</b>  |                                      |              |   |
| <b>Angioedema and Severe Allergic Reaction:</b> 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  |                                      |              | ✓   |
| <b>Bronchospasm:</b> difficulty breathing and coughing, chest tightness, wheezing or whistling sound when breathing  |                                      |              | ✓   |
| <b>Chest pain</b>  |                                      | ✓            |   |
| <b>Depression</b> (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 |                                      | ✓            |   |
| <b>Edema</b> (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  | ✓                                    |              |   |
| <b>Erectile Dysfunction:</b> unable to get or keep an erection   | ✓                                    |              |   |
| <b>Hyperkalemia</b> (too much potassium in the Blood): irregular heartbeat, muscle weakness and generally feeling unwell   |                                      | ✓            |   |
| <b>Hyponatremia</b> (Low sodium in the Blood) that may lead to:<br><b>-dehydration</b> (happens when your 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 |   |
| doesn't have as much water as it needs; leading to extreme thirst),<br>- <b>low blood pressure:</b> blurred vision, dizziness, light-headedness, fainting  |                                      |              |   |
| <b>Kidney problems:</b> change in frequency of urination, nausea, vomiting, swelling of extremities, fatigue   |                                      | ✓            |   |
| <b>Palpitations</b> (fast beating, fluttering or pounding heart): skipping beats, beating too fast, pounding, fluttering rapidly   |                                      | ✓            |   |
| <b>Pemphigoid/Pemphigus:</b> blisters of different sizes develop on the skin   |                                      |              | ✓   |
| <b>RARE</b>  |                                      |              |   |
| <b>Acute renal failure</b> (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  |                                      |              | ✓   |
| <b>Hypochloremia</b> (low chloride in the Blood): diarrhea, unusual tiredness or weakness, dehydration   |                                      | ✓            |   |
| <b>Hypomagnesaemia</b> (low magnesium in the Blood): shaking, unusual tiredness or weakness, muscle cramps, numbness, eye movements problems, seizures.  |                                      | ✓            |   |
| <b>SIADH</b> (syndrome of inappropriate antidiuretic hormone secretion): dark urine, nausea, vomiting, muscle cramps, confusion and fits (seizures)  |                                      | ✓            |   |
| <b>Worsening of Psoriasis</b> (chronic skin disease): red, itchy, scaly patches of the skin  |                                      | ✓            |   |
| <b>VERY RARE</b>   |                                      |              |   |
| <b>Blood disorders:</b> infections, fatigue, fever, aches, pains, and flu-like symptoms, bruising, bleeding, fatigue and weakness, small purple or red dots under the skin.  |                                      | ✓            |   |
| <b>Cerebrovascular accident/Stroke</b> (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 |                                      |              | ✓   |

| 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 |   |
| speaking, or lethargy, dizziness, fainting, vomiting, trouble understanding, trouble with walking and loss of balance   |                                      |              |   |
| <b>Erythema multiforme</b> (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.  |                                      |              | ✓   |
| <b>Liver Problems:</b> yellowing of the skin or eyes, dark urine, abdominal pain, nausea, vomiting, loss of appetite  |                                      | ✓            |   |
| <b>Myocardial Infarction</b> (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   |                                      |              | ✓   |
| <b>Pancreatitis</b> (inflammation of the pancreas): upper abdominal pain, fever, rapid heartbeat, nausea and vomiting, tenderness when touching the abdomen   |                                      |              | ✓   |
| <b>Stevens-Johnson Syndrome (SJS), Toxic Epidermal Necrolysis (TEN)</b> (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 |                                      |              | ✓   |
| <b>UNKNOWN</b>  |                                      |              |   |
| <b>Eye problems:</b><br>- <b>Myopia</b> (near sightedness): blurred vision, difficulty focusing on objects far away, need to squint, headache caused by eyestrain, fatigue<br>- <b>Glaucoma:</b> blurred vision, halos around lights, eye pain and redness, nausea and vomiting, severe headache  |                                      |              | ✓   |

| 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 |   |
| <b>Hyperglycemia</b> (high blood sugar): increased thirst, frequent urination, dry skin, headache, blurred vision and fatigue   | ✓                                    |              |   |
| <b>Increased Levels of Uric Acid in the Blood:</b> swelling and redness in the joints   |                                      | ✓            |   |
| <b>Possible worsening of pre-existing lupus</b> (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 |                                      |              | ✓   |
| <b>Raynaud's phenomenon</b> (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  |                                      | ✓            |   |
| <b>Rhabdomyolysis</b> (breakdown of damaged muscle): muscle pain that you cannot explain, muscle tenderness or weakness, red-brown (tea-coloured) urine   |                                      | ✓            |   |
| <b>Torsade de pointes:</b> 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 (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.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.

- PERINDOPRIL ERBUMINE / INDAPAMIDE and PERINDOPRIL ERBUMINE / INDAPAMIDE HD: store at room temperature (15°C - 30°C).
- PERINDOPRIL ERBUMINE / INDAPAMIDE and PERINDOPRIL ERBUMINE / INDAPAMIDE 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 PERINDOPRIL ERBUMINE / INDAPAMIDE and PERINDOPRIL ERBUMINE / INDAPAMIDE HD:

- 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.sivem.ca](http://www.sivem.ca), or by calling 1-855-788-3153.

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