PART III: CONSUMER INFORMATION

Pr PRO-FUROSEMIDE
Furosemide Tablets USP

This leaflet is part III of a three-part "Product Monograph" published for PRO-FUROSEMIDE in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about PRO-FUROSEMIDE. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:
PRO-FUROSEMIDE has been prescribed to you by your health provider to treat your edema (water retention) or hypertension (high blood pressure).

What it does:
PRO-FUROSEMIDE belongs to a group of medicines known as diuretic drugs which improve the elimination of water and salts (electrolytes) in the urine.

When it should not be used:
Do not use PRO-FUROSEMIDE if you are allergic to it or to any of the components of its formulation (for list of components see the section on "What the nonmedicinal ingredients are"), or to any sulfonamide-derived drugs. Ask your physician or pharmacist if you are not sure what sulfonamide-derived drugs are.

Do not use PRO-FUROSEMIDE if:

- You are suffering kidney failure, hepatic (liver) coma or precoma disease.
- You have electrolyte depletion (loss of blood salts e.g. dehydration, hot weather, excessive sweating…) or severe hyponatremia (low blood sodium), hypokalemia (low blood potassium), hypovolemia (low blood volume), hypotension (low blood pressure) or dehydration until your electrolytes and fluid balance are restored.
- Your newborn infant has jaundice (yellowing of the skin and/or eyes) or infants suffering from certain diseases (e.g. Rh incompatibility, familial non-hemolytic jaundice (yellowing of the skin and/or eyes without evidence of liver damage)).
- Do not breastfeed if you intend to use PRO-FUROSEMIDE.

What the medicinal ingredient is:
Furosemide

What the nonmedicinal ingredients are:
20 mg tablets: colloidal silicon dioxide, croscarmellose sodium, lactose monohydrate, magnesium stearate and microcrystalline cellulose.

40 mg and 80 mg tablets: colloidal silicon dioxide, croscarmellose sodium, D & C Yellow # 10 Aluminum Lake 14-18%, lactose monohydrate, magnesium stearate, microcrystalline cellulose and Sunset Yellow Aluminum Lake 40%.

What dosage forms it comes in:
Tablets of 20 mg, 40 mg and 80 mg.

WARNINGS AND PRECAUTIONS

PRO-FUROSEMIDE IS A VERY STRONG WATER PILL WHICH IF GIVEN IN EXCESSIVE AMOUNTS CAN LEAD TO A PROFOUND WATER AND ELECTROLYTE LOSS FROM THE BODY. THEREFORE, CAREFUL MEDICAL SUPERVISION IS REQUIRED. THE DOSE AND DOSE SCHEDULE HAVE TO BE ADJUSTED TO THE INDIVIDUAL PATIENT'S NEEDS.

BEFORE you use PRO-FUROSEMIDE talk to your health provider if:

- You have decreased blood pressure.
- You have liver disease or disorder.
- You have kidney disease or disorder.
- It is suspected you might be diabetic (high blood sugar).
- You have decreased ability to pass urine.
- You had an organ transplant.
- You have gout.
- You have been told by the doctor that you suffer from a narrowing of the arteries that supply your heart or brain.
- You have recently suffered from excess vomiting or diarrhea.
- You intend to have a surgery and general anesthesia (even at the dentist's office), as there may be a sudden fall in blood pressure associated with general anesthesia.
- You are breastfeeding. PRO-FUROSEMIDE is passed to the infant during breastfeeding. Do not breastfeed if you intend to take PRO-FUROSEMIDE.
- You are pregnant, or think you might be pregnant.
- You intend to change your eating habits.

- You are less than 18 years old.
- You are older than 61 years old.

When administered to children, PRO-FUROSEMIDE therapy should be started in the hospital, in carefully selected patients, under close observation with frequent blood tests to measure electrolytes such as sodium, potassium, chloride, magnesium and calcium.

For elderly patients, (over 61 years old), the dose selection should be cautious, usually starting at the low end of dosage range, reflecting the greater frequency of decreased liver, kidney or heart function.

Studies in elderly patients with dementia have shown that taking PRO-FUROSEMIDE with risperidone is associated with a higher rate of death.

The administration of PRO-FUROSEMIDE to diabetic patients may result in possible decrease of diabetic control. Dosage adjustments of the antidiabetic agent may be needed.

There have been cases of ringing in the ears, reversible and non-reversible deafness especially in children. This is most true when the patient has severe kidney disease or is taking drugs that are known to sometimes damage the ears while they are taking PRO-FUROSEMIDE. Your doctor will decide if PRO-FUROSEMIDE is the right medication for you/your child based on your particular condition.

PRO-FUROSEMIDE should not be used in pregnant women or in women of childbearing potential unless in the opinion of the attending physician the benefits to the patient outweigh the possible risk to the foetus. Treatment during pregnancy requires monitoring of fetal growth by your doctor.

If you are suffering from hyperuricemia (high uric acid levels in your blood), taking PRO-FUROSEMIDE can sometimes make a gout attack more likely.

Almost all patients can drive or operate machinery while taking PRO-FUROSEMIDE, but you should not perform these tasks, which may require attention, until you know how you tolerate your medicine.

INTERACTIONS WITH THIS MEDICATION

Before using PRO-FUROSEMIDE, tell your health provider about medication you are currently taking. This way appropriate adjustment and decision can be taken for your treatment with PRO-FUROSEMIDE.
Below are drugs or drug classes that may interact with PRO-FUROSEMIDE. These include:

- Drugs to reduce blood pressure (eg. ACE inhibitors, angiotensin II receptor antagonist).
- Diuretics (waterpills), including ethacrynic acid
- Pressor amines such as epinephrine (a medication used to treat life-threatening allergic reactions).
- Medication to treat diabetes, including insulin. The administration of PRO-FUROSEMIDE to diabetic patients may result in possible decrease of diabetic control. Dosage adjustments of the antidiabetic agent may be needed.
- Theophylline, a medication used to treat asthma, chronic bronchitis, and other lung diseases.
- Cisplatin (anti-cancer drug)
- Probenecid (medicine used to treat gout).
- Antibiotics (e.g cephalosporins, aminoglycosides)
- Certain pain and anti-inflammatory drugs (e.g non-steroidal anti-inflammatory drugs [NSAIDs], acetyl-salicylic acid, indomethacin)
- Drugs used in the treatment of rheumatoid arthritis (methotrexate, cyclosporin).
- Drugs used to treat epilepsy (e.g. phenytoin, carbamazepine, phenobarbital).
- Risperdal, a drug used to treat dementia.
- Lithium (medicine used to treat bipolar depression).
- Sucralfate (antacid drug)
- Sedatives such as phenobarbital or chloral hydrate
- Stimulant laxatives and drugs which may induce low potassium levels (hypokalemia) such as glucocorticoids, and medicine derived from licorice (eg. carbenoxolone).
- Drugs known to be harmful to the ear (ototoxic) as for instance aminoglycosides antibiotics, ethacrynic acid (a “water pill”) and cisplatin (a drug used to treat some types of cancer).
- Drugs known to be harmful to the kidney.
- Substances used during certain radiological investigations (radiocontrast agents).

- Digitalis (digoxin)
- Certain steroids

PROPER USE OF THIS MEDICATION

During long-term therapy a high-potassium diet may be recommended. You should not be on a strict salt restricted diet. Potassium supplements may be required. Your doctor will monitor your blood tests for blood sugar, potassium and other electrolytes and to monitor liver and kidney function. This is especially important if you have other medical conditions such as diabetes, take other medications or the patient is an infant or child.

Usual dose:

Adults (oral) for edema and high blood pressure:

It is important that you take PRO-FUROSEMIDE as prescribed by your doctor.

Usually your doctor will prescribe PRO-FUROSEMIDE tablets at a dose of 20 to 80 mg per day, which you could take as single or 2-3 divided doses, based on the type of administration your physician considers to be the most appropriate for your condition.

Maximum daily dose: 200 mg.

Swallow the tablets whole with a glass of water.

When prescribed to children, furosemide is usually administered in the form of a solution and at a dose that will be determined by the health care provider. Furosemide oral solution should be taken on an empty stomach.

You should always respect the prescribed interval between the doses. Never change the dose of PRO-FUROSEMIDE you are taking unless your doctor tells you to.

This drug is specifically prescribed for you or a child in your care. Do not give it to others, even if they have the same symptoms, and you yourself must not use it for any condition than the one for which it was prescribed.

Pediatrics (oral):

PRO-FUROSEMIDE therapy should be instituted in the hospital, in carefully selected patients, under close observation with frequent monitoring of blood tests including electrolytes. The doctor will decide what is the best dose for each child.

Orally, the initial dose should be in the range of 0.5 to 1.0 mg/kg body weight.

The total daily dose (given in divided doses of 6 to 12 hours apart) should not exceed 2 mg/kg orally. In the newborn and in premature babies, the daily dose should not exceed 1 mg/kg.

Overdose:

If you think you have taken too much PRO-FUROSEMIDE, contact your healthcare professional, hospital emergency department or regional poison control centre immediately, even if there are no symptoms.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Along with its beneficial effects, PRO-FUROSEMIDE like all other drugs may sometimes cause undesirable effects. These may include: blurring of vision, constipation, diarrhea, dizziness, dry mouth, fatigue, tachycardia, arrhythmia (heart rhythm disturbance), feeling of pressure in the head, increase in the amount and frequency of your urine, leg cramps, mental confusion, nausea, sweating, thirst, vomiting, hepatic encephalopathy (altered mental state due to liver disease). Talk to your doctor or pharmacist if you experience any of the above.

Stop taking PRO-FUROSEMIDE and contact your doctor immediately if you experience an allergic reaction or any severe side effect.

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 attention
	Only if severe	In all cases	
Hearing problems; deafness, sometimes non-reversible		√	
Fever, sore throat, fatigue, lesions in the mouth or on the lips			√
Skin rash and/or blistering			√

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 attention
	Only if severe	In all cases	
Hives and/or itching			√
Abdominal pain		√	
Difficulty to urinate			√
Low blood pressure (hypotension): dizziness when rising to a standing position, impaired concentration and lightheadedness		√	
Yellow coloration of the skin (jaundice)			√
Dehydration and/or abnormal blood tests: dryness of the mouth, thirst, weakness, dizziness, lethargy, drowsiness, restlessness, muscle pain or cramps, muscular fatigue, hypotension, racing or irregular heartbeats, nausea and vomiting, sweating, increases in blood sugar levels, increased urination, mental confusion, headache			√
Pseudo-Barterr syndrome: abnormal blood tests, fatigue, muscle weakness, diarrhea, dehydration, increased thirst, increased urination, low blood pressure, irregular heartbeats			√
Blurred vision		√	
Allergic reactions: eyes sensitive to light, tingling of fingers or toes, fever			√
Blood clots: pain, swelling tenderness in your leg or arm, warm, red skin and a heavy feeling in the affected area			√

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 attention
	Only if severe	In all cases	
Failure of the kidneys: weakness, trouble breathing, swelling, fast or irregular heartbeat, confusion, decrease or inability to urinate, loss of appetite, coma and death			√
In premature babies: discoloured urine and/or blood in the urine/diaper, fever and chills, vomiting, excessive crying or other signs the baby is in pain			√
In premature babies: poor weight gain		√	

Although not all of the above side effects are common, if you experience one of these while you are in the hospital or at home, talk to your doctor or pharmacist immediately.

This is not a complete list of side effects. For any unexpected effects while taking PRO-FUROSEMIDE, contact your doctor or pharmacist.

HOW TO STORE IT

Store your tablets at room temperature (15°C to 30°C). Protect from light.

There is an expiration date on the label. Do not use the medicine after this date.

Return any leftover tablets to the pharmacist, unless the doctor tells you to keep them at home.

As with all medicines, keep PRO-FUROSEMIDE out of reach and sight of children.

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.

MORE INFORMATION

If you want more information about PRO-FUROSEMIDE:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this consumer information by visiting the Health Canada website (https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html); or by contacting Pro Doc Ltée at 1-800-361-8559, www.prodoc.qc.ca or info@prodoc.qc.ca.

This leaflet was prepared by
Pro Doc Ltée, Laval, Québec, H7L 3W9

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