PART III: CONSUMER INFORMATION

PrINSPRA®
eplerenone tablets

This leaflet is Part III of a three-part "Product Monograph" published when INSPRA was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about INSPRA. Contact your doctor or pharmacist if you have any questions about the drug. Please read this information carefully.

ABOUT THIS MEDICATION

What the medication is used for:

In adults, INSPRA is used alone or combined with other drugs for patients with hypertension (high blood pressure) to lower blood pressure.

In adults, INSPRA is used in combination with other drugs for patients with heart failure:

- to prevent worsening heart failure
- to prevent death from heart failure
- to reduce the risk of hospitalizations for heart failure

If you are an adult under 75 years old with heart failure, INSPRA may reduce the risk of death. This is not necessarily true for patients 75 years old and older.

What it does:

Your body makes a substance called aldosterone. It is important for controlling blood pressure and heart function. Sometimes, high levels of aldosterone can cause changes in your body that may worsen heart failure. INSPRA works by blocking the actions of aldosterone, and can help prevent heart failure from getting worse.

When it should not be used:

Do not use INSPRA if you:

- are hypersensitive (allergic) to INSPRA or to any of the other ingredients of INSPRA (see below for the non-medicinal ingredients);
- have high levels of potassium in your blood;
- are taking potassium sparing diuretics (certain types of water tablets);
- have severe liver impairment;
- have heart failure and severe kidney impairment;
- have hypertension and moderate kidney impairment
- are taking other medications that may affect the elimination of INSPRA, such as:
  - ritonavir or nelfinavir (antiviral medication for treating HIV);
  - clarithromycin, or telithromycin (antibiotics used to treat bacterial infections);
  - ketoconazole or itraconazole (medicines that are used to treat fungal infections);
  - nefazadone (used to treat depression);
  - potassium supplements.

What the medicinal ingredient is:

Eplerenone

What the nonmedicinal ingredients are:

- lactose
- microcrystalline cellulose
- croscarmellose sodium
- hypromellose
- sodium lauryl sulphate
- talc
- magnesium stearate
- titanium dioxide
- polyethylene glycol
- polysorbate 80
- iron oxide yellow
- iron oxide red.

What dosage forms it comes in:

INSPRA tablets are available in 25 mg and 50 mg strengths.

WARNINGS AND PRECAUTIONS

BEFORE you use INSPRA tell your doctor or pharmacist if:

- you are pregnant or if you are planning to become pregnant. The effects of INSPRA have not been evaluated during pregnancy. Ask your doctor or pharmacist for advice before taking any medicine.
- you are breast-feeding or intend to breast-feed;
- you have kidney or liver disease;
- you are diabetic;
- you are taking lithium (usually given as a mood stabilizing medication);
- you are using potassium supplements or salt substitutes containing potassium.

Please contact your doctor if you are taking any of the above medicines, or have taken them in the past.

You may feel dizzy after taking this medicine. If this happens, tell your doctor about it and do not drive or operate machinery.

INTERACTIONS WITH THIS MEDICATION

Certain medications can affect the way that INSPRA is broken down by the body. Interaction with other drugs is possible. Please inform your doctor if you are taking any of the following medicines (see also "When it should not be used"):

- ketoconazole, itraconazole or fluconazole (used to treat fungal infections);
- verapamil or diltiazem (used for heart problems and/or high blood pressure);
- digoxin or amiodarone (used to treat particular heart conditions including irregular heart rhythms);
- angiotensin converting enzyme inhibitors which are any

medication with generic names ending with "pril" (used for high blood pressure or heart conditions);
- angiotensin II receptor antagonists, which are any medication with generic names ending with "sartan" (used for high blood pressure, or particular kidney conditions);
- potassium sparing diuretics (certain water tablets used to treat fluid retention) (see also "When it should not be used");
- potassium supplements (salt tablets);
- herbal preparations containing large amounts of potassium (such as Noni fruit or juice, dandelion);
- saquinavir, ritonavir or nelfinavir (antiviral medication for treating HIV);
- erythromycin, clarithromycin, telithromycin, or rifampicin (antibiotics used to treat bacterial infections);
- lithium (usually given as a mood stabilizing medication);
- nefazadone and St John's Wort (used to treat depression);
- carbamazepine, phenytoin and phenobarbital (used to treat epilepsy);
- Non-steroidal anti-inflammatory drugs (certain pain killers, such as ibuprofen and other pain relievers).

Tell your doctor or pharmacist if you are taking any other medications, including prescription, non-prescription and natural health products.

PROPER USE OF THIS MEDICATION

Your doctor and pharmacist will tell you how to take your medicine. Carefully follow the instructions given to you by your doctor and pharmacist.

INSPRA tablets may be taken with or after a meal or on an empty stomach. Swallow the tablets with a glass of water without chewing.

INSPRA is not recommended for children.

Usual dose:

The usual starting dose will depend on the potassium level in your body and your kidney condition which will be assessed by your doctor.

In people with normal or near normal kidney function, *for heart failure* the usual starting dose is one 25 mg tablet once daily, increasing to one 50 mg tablet once daily in about 4 weeks, as instructed by your doctor. *For hypertension*, the usual dose is 50 mg tablet once daily.

The maximum daily dose for heart failure is 50 mg and for hypertension, it is 100 mg.

Lower doses will be used in people with elevated potassium in the blood or weaker kidney function.

Blood potassium levels should be measured before starting INSPRA therapy, within the first week and at one month after the start of treatment or after a change in dose. The dose may be adjusted by your doctor, depending on the potassium levels in your blood. It is very important that you comply with your doctor's recommendations particularly regarding the laboratory test which may be prescribed.

It is important to keep taking INSPRA as prescribed unless your doctor tells you to stop your treatment.

Overdose:

If you take more INSPRA than you should, tell your doctor or pharmacist immediately.

If you think you have taken too much INSPRA contact your doctor, nurse, pharmacist, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed Dose:

If you forget to take a tablet take it as soon as you remember. If it is almost time to take the next tablet, do not take the tablet you have missed. Instead, take the next tablet when it is due and afterwards, continue to take your tablets as your doctor has prescribed for you. Do not take a double dose to make up for the forgotten tablet.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Side effects may include headache. The most common side effects seen with INSPRA are related to increased blood potassium levels.

INSPRA 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 call your doctor or pharmacist
		Only if severe	In all cases	
Common	**Increased levels of potassium in the blood:** Irregular heartbeats, muscle weakness and generally feeling unwell		✓	

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 call your doctor or pharmacist
		Only if severe	In all cases	
Uncommon	**Dehydration:** headaches, dizziness or fainting	✓		
	Blood clot in the leg (arterial leg thrombosis): swelling, pain and redness in a leg that can be warm to touch.		✓	
	Low Blood Pressure: feeling of lightheadedness or fainting especially when getting up from a lying or sitting position	✓		
	Hypothyroidism: constipation, weight gain, fatigue, intolerance to cold	✓		
	Gastroesophageal reflux disease (GERD): heartburn, regurgitation and trouble swallowing	✓		
	Pancreatitis (inflammation of the pancreas): abdominal pain that lasts and gets worse when you lie down, nausea, vomiting		✓	
	chest pain		✓	
	angina		✓	
	breathing difficulty		✓	

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 call your doctor or pharmacist
		Only if severe	In all cases	
	changes in rhythm or pace of heart beat		✓	
	less urine than is normal for you		✓	
	swelling of the hands, feet, ankles, face, lips, mouth, or throat (may cause difficulty in swallowing or breathing)			✓
	hives		✓	
	fainting		✓	
	yellowing of the skin and eyes, also called jaundice		✓	
	weight gain		✓	

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

HOW TO STORE IT

Always keep medicine well out of sight and reach of children.
Store at controlled room temperature (15–30ºC).

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 on 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: http://www.viatris.ca or by contacting the sponsor, BGP Pharma ULC, at: 1-844-596-9526.

This leaflet was prepared by BGP Pharma ULC.

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