IMPORTANT: PLEASE READ

PART III: CONSUMER INFORMATION

PrRANITIDINE - 150
PrRANITIDINE - 300
Ranitidine Tablets USP
150 mg and 300 mg

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

ABOUT THIS MEDICATION

What the medication is used for:
RANITIDINE, also known as ranitidine hydrochloride is used to treat stomach or intestinal ulcers and prevent their return. It can relieve discomfort from ulcer pain and the heartburn associated with acid reflux.

What it does:
RANITIDINE belongs to a group of medicines called H_2-receptor site antagonists. It acts by blocking histamine receptors that are present on the cells in the stomach lining thereby reducing the amount of acid produced by these cells.

When it should not be used:
Do not take RANITIDINE if you have previously had an allergic reaction to the medicine or any of the non-medicinal ingredients of the product.

What the medicinal ingredient is:
Ranitidine Hydrochloride

What the important non-medicinal ingredients are:
Microcrystalline cellulose, hydroxypropyl methylcellulose, polydextrose, titanium dioxide, magnesium stearate, colloidal silicon dioxide, vanillin and carnauba wax.

What dosage forms it comes in:
Tablets, 150 mg and 300 mg

WARNINGS AND PRECAUTIONS

Before you use RANITIDINE talk to your doctor or pharmacist if:

- you have severe decreased renal function.
- you have lung disease, diabetes or a compromised immune system.
- you are pregnant or breast-feeding.
- you are older than 65 years of age, for your doctor to rule out the possibility of stomach cancer. Also, make sure your doctor knows if you are taking non-steroidal anti-inflammatory drugs (NSAIDs).
- occurrence of a gastric ulcer is suspected . RANITIDINE can mask the symptoms of stomach cancer and therefore delay the diagnosis of this condition.

This medicine should not be used if you have acute porphyria (a rare blood disorder).

Experience with RANITIDINE in children below 8 years of age is limited.

INTERACTIONS WITH THIS MEDICATION

Drugs that may interact with this medicine:

- Non-steroidal anti-inflammatory drugs;
- Ketoconazole;
- Hypoglycemic drugs;
- Theophylline;
- Sucralfate.

If you have any concerns regarding drug interactions please consult your pharmacist or physician.

PROPER USE OF THIS MEDICATION

Usual Dose:
Duodenal and benign gastric ulcer: 300 mg once daily at bedtime or 150 mg twice daily. In duodenal ulcers, when more rapid healing is desired: 300 mg twice daily for 4 weeks.

Maintenance treatment: Duodenal and benign gastric ulcer: 150 mg once daily at bedtime. **Duodenal ulcer (smoker):** 300 mg nightly. **Reflux esophagitis:** 300 mg once daily at bedtime or 150 mg twice daily for up to 8 weeks. In patients with moderate to severe esophagitis, may increase to 150 mg four times daily.

Post-operative peptic ulcer: 150 mg twice daily.

Zollinger-Ellison Syndrome: Initially 150 mg three times daily. Some patients may require more frequent dosing.

NSAID-induced lesions (both ulcers and erosions) and their gastrointestinal symptoms and prevention of their recurrence: 150 mg twice daily while continuing NSAID therapy.

Prophylaxis of Acid Aspiration Syndrome: 150 mg the evening prior to anesthesia or 2 hours prior to anesthesia.

Prophylaxis of hemorrhage from stress ulceration or prophylaxis of recurrent hemorrhage from bleeding peptic ulcers: 150 mg twice daily for patients on oral feeding.

Elderly patients should start at the lowest recommended dose and be adjusted as necessary.

Overdose:
If you take more than the prescribed dose please consult your physician or Emergency room as soon as possible.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like other medications, RANITIDINE can cause some side effects. These side effects are most likely to be minor and temporary.

Do not be alarmed by this list of possible side effects. You may not experience any of them. If any of these side effects are experienced, do not hesitate to report them to your doctor.

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	Headache	√		
	Diarrhea	√		
	Nausea/vomiting	√		
Uncommon	Dizziness	√		
	Sleepiness or lack of sleep	√		
	Vertigo	√		
	Blurred vision		√	
	Changes to heart rate (increase & decrease) and rhythm		√	
	Constipation	√		
	Abdominal discomfort/pain	√		
	Pain in the muscles and joints		√	
	Tenderness/ soreness of the breasts in males		√	
	Skin rash, redness of the skin or hair loss		√	
	Allergic reactions (including chest pain, coughing, fever, rash, swelling, hives, and low blood pressure)		√	√

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

HOW TO STORE IT

Store between 15-30ºC (59-86ºF). Protect from light.

REPORTING SUSPECTED SIDE EFFECTS

To monitor drug safety, Health Canada collects information on serious and unexpected effects of drugs. If you suspect you have had a serious or unexpected reaction to this drug you may notify Health Canada by:

toll-free telephone: 866-234-2345
toll-free fax 866-678-6789
By email: cadrmp@hc-sc.gc.ca

By regular mail:
Canadian Adverse Drug Reaction Monitoring Program (CADRMP)
Health Canada
Address Locator: 0201C2
Ottawa, ON K1A 1B9

NOTE: Before contacting Health Canada, you should contact your physician or pharmacist.

MORE INFORMATION

For more information, please contact your doctor, pharmacist or other healthcare professional. This leaflet plus the full product monograph, prepared for health professionals, can be obtained by Pro Doc Ltée at 1-800-361-8559, http://www.prodoc.qc.ca or info@prodoc.qc.ca.

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

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