PART III: CONSUMER INFORMATION

Pr RANITIDINE INJECTION USP
Ranitidine (as Ranitidine hydrochloride) Injection USP
25 mg/ml
sterile

This leaflet is part III of a three-part "Product Monograph" published when Ranitidine Injection USP 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 Injection USP. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:

- to heal ulcers in the stomach, or the part that it empties into (the duodenum).
- to prevent stomach ulcers which may be caused by medicines called non-steroidal anti-inflammatory drugs (NSAIDs), often used to treat arthritis
- to prevent ulcers from bleeding
- to heal or stop problems caused by acid in the food pipe (esophagus) or too much acid in the stomach. This can cause pain or discomfort sometimes known as indigestion or heartburn
- to stop acid coming up from the stomach while under anaesthetic during an operation

What it does:
Ranitidine Injection USP belongs to a group of medicines called H2-receptorblockers. It works by reducing the amount of acid in your stomach.

When it should not be used:
Don't take Ranitidine Injection USP if you are allergic (hypersensitive) to ranitidine or any other ingredients of Ranitidine Injection USP (see **What the nonmedicinal ingredients are**).

What the medicinal ingredient is:
ranitidine hydrochloride

What the important nonmedicinal ingredients are:
Each mL of Ranitidine Injection USP contains ranitidine (as hydrochloride) 25 mg, dibasic sodium phosphate 2.4 mg, monobasic potassium phosphate 0.96 mg, phenol (as preservative) 5 mg, hydrochloric acid and/or sodium hydroxide to adjust pH and water for injection.

What dosage forms it comes in:
Ranitidine Injection USP is available in 2 mL single dose vials, boxes of 10, and in 50 mL and 100 mL Pharmacy Bulk Vials, boxes of 1.

WARNINGS AND PRECAUTIONS

BEFORE you use Ranitidine Injection USP talk to your doctor or pharmacist if you:

- have stomach cancer
- have kidney disease, your doctor may lower your dose of Ranitidine Injection USP
- have a rare condition called acute porphyria (a blood disease)
- have lung disease
- are diabetic
- have any problems with your immune system
- have a history of heart problems
- have had stomach ulcers before and you are taking Non-Steroidal Anti-Inflammatory (NSAID) medicines
- are pregnant, planning to become pregnant, breastfeeding or planning to breastfeed
- are taking any other medications including NSAIDs (see **Interactions with this Medication**).

Under rare circumstances supervised by the doctor, H_2- receptor antagonists such as Ranitidine Injection USP might be used for long periods. Long term use of H_2-receptor antagonists may prevent normal absorption of vitamin B12 from the diet and could lead to vitamin B12 deficiency. Talk to your doctor.

INTERACTIONS WITH THIS MEDICATION

Tell your doctor or pharmacist if you're taking any other medicines, if you've taken any recently, or if you start taking new ones. This includes medicines bought without a prescription. Some medicines can affect how Ranitidine Injection USP works, or make it more likely that you'll have side effects. Ranitidine Injection USP can also affect how some other medicines work.
Drugs that may interact with Ranitidine Injection USP include:

- procainamide or n-acetylprocainamide (used to treat heart problems)
- warfarin (used to thin the blood)
- triazolam (used to treat insomnia)
- midazolam (a sedative that may be given just before an operation)
- ketoconazole (used to treat fungal infections)
- atazanavir or delaviridine (used to treat HIV)
- gefitnib (used to treat lung cancer)
- Non-Steroidal Anti-Inflammatory (NSAID) medicines (used to treat pain and inflammation)
- sucralfate (used to treat ulcers). Your doctor may advise that you take high doses or oral sucralfate (e.g. 2g) at least 2 hours after Ranitidine Injection USP administration.

PROPER USE OF THIS MEDICATION

Ranitidine Injection USP is not self administered by an individual. It should be administered under the supervision of a health professional.

Usual dose:
The usual dose is 50 mg every 6 to 8 hours, as a single injection into a muscle.
Alternatively, different doses may be given to you intravenously by slow infusion or continuous infusion, depending on what condition you are being treated for.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Side effects may include:
- allergic reactions
- skin rash
- inflammation of blood vessels (vasculitis)
- inflammation of the pancreas (pancreatitis)
- inflammation of the liver (hepatitis), sometimes with yellowing of the whites of the eyes or skin (jaundice)
- inflammation in the kidney (interstitial nephritis)
- slow, fast or irregular heartbeat
- diarrhea, constipation, nausea, vomiting, stomach pain
- feeling confused, depressed, or excited, or seeing or hearing things that are not really there (hallucinations), trouble sleeping (insomnia); feeling sleepy (somnolence)
- joint or muscle pain, malaise, uncontrolled movement
- headache, dizziness, blurred vision
- unusual hair loss or thinning (alopecia)
- unable to get or maintain an erection (impotence)
- unusual secretion of breast milk or breast enlargement in men

If you have any concerns about the side effects, tell your doctor, nurse or pharmacist.

Side effects that may show up in your blood tests:
- changes to liver function
- low levels of white blood cells
- decrease in number of blood platelets (cells that help blood to clot)
- decrease in number of all types of blood cells
- small increase in the level of creatinine (a waste product) in your blood

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	
Rare	Hypersensitivity Reaction Raised and itchy rash (hives), swelling, sometimes of the face or mouth (angioedema), chest pain, shortness of breath, unexplained fever, wheezing or difficulty in breathing, feeling faint, especially when standing up, collapse			✓
Very rare	Serious Skin Reactions Skin rash, which may blister, and look like small targets (central dark spots surrounded by a paler area, with a dark ring around the edge)			✓
Very rare	Hepatitis Yellowing of the skin or whites of the eyes, dark or tea coloured urine, pale coloured stools/ bowel movements, nausea/ vomiting, loss of appetite, pain, aching or tenderness on right side below the ribs			✓
Very rare	Cardiovascular Slow, fast or irregular heartbeat			✓

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

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 0701D
    Ottawa, Ontario
    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 by contacting the sponsor, Sandoz Canada Inc., at:

1-800-361-3062

or by written request at:
145 Jules-Léger
Boucherville QC
J4B 7K8

Or by e-mail at :
medinfo@sandoz.com

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