

**PART III: CONSUMER INFORMATION**

**Pr APO-RANITIDINE  
Ranitidine Tablets USP  
150 mg and 300 mg**

**This leaflet is part III of a “Product Monograph” published when APO-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 APO-RANITIDINE. 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:**

APO-RANITIDINE belongs to a group of medicines called H<sub>2</sub>-receptor blockers. It works by reducing the amount of acid in your stomach.

**When it should not be used:**

Do not take APO-RANITIDINE if you are allergic (hypersensitive) to ranitidine or any other ingredients of APO-RANITIDINE (see What the nonmedicinal ingredients are).

**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:**

Each tablet contains either 150 mg or 300 mg ranitidine (as ranitidine hydrochloride)

**WARNINGS AND PRECAUTIONS**

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

- have stomach cancer
- have kidney disease, your doctor may lower your dose of APO-RANITIDINE
- have a rare condition called acute porphyria (a blood disease)
- have lung disease
- are diabetic
- have any problems with your immune system
- 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<sub>2</sub>-receptor antagonists such as APO-RANITIDINE might be used for long periods. Long term use of H<sub>2</sub>-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 APO-RANITIDINE works, or make it more likely that you'll have side effects. APO-RANITIDINE can also affect how some other medicines work.

Drugs that may interact with APO-RANITIDINE 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)

**IMPORTANT: PLEASE READ**

- gefitinib (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 APO-RAMITIDINE administration.
- 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

**PROPER USE OF THIS MEDICATION**

**Usual Adult Dose:**

Always take APO-RANITIDINE exactly as your doctor has told you to. Check with your doctor or pharmacist if you're not sure.

The usual dose is either:

- 150 mg in the morning and 150 mg in the evening or,
- 300 mg at bedtime

Your exact dose will depend on your particular stomach condition. Your doctor will tell you the dose you should take. Swallow each tablet whole with some water. **Overdose:** If you take too much Apo-RANITIDINE, contact your doctor or pharmacist for advice .If possible; show them the APO-RANITIDINE pack.

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

**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

**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 emergency medical attention
	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		√

## IMPORTANT: PLEASE READ

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

## HOW TO STORE IT

Store between 15°C - 30°C (59 °F -86°F). Protect from light. Keep out of reach and sight of children.

### Reporting Side Effects

You can help improve the safe use of health products for Canadians by reporting serious and unexpected side effects to Health Canada. Your report may help to identify new side effects and change the product safety information.

#### 3 ways to report:

- Online at [MedEffect](#);
- By calling 1-866-234-2345 (toll-free);
- By completing a Consumer Side Effect Reporting Form and sending it by:
  - Fax to 1-866-678-6789 (toll-free), or
  - Mail to: Canada Vigilance Program  
Health Canada,  
Postal Locator 0701E  
Ottawa, ON, K1A 0K9

Postage paid labels and the Consumer Side Effect Reporting Form are available at [MedEffect](#).

*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

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 contacting DISpedia, Apotex's Drug Information Service at:

1-800-667-4708

This leaflet can also be found at:  
<http://www.apotex.ca/products>.

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