

CONSUMER INFORMATION
Product Monograph Part III

PANTOLOC MTM
pantoprazole magnesium
40 mg, enteric-coated tablets

ALTANA Pharma Inc.

Submission Control No. 091462

The Consumer Information Section (Part III) of the Product Monograph for PANTOLOC MTM has been submitted by the drug sponsor and is attached for your information.

The attached version accompanied the Notice of Compliance issued on April 22, 2005, and does not necessarily reflect the most current information for the product.

For the most up-to-date product information, please consult your health care professional.

Due to the fact that the information originated with an organization that is not subject to the *Official Languages Act*, the document may only appear in the language in which it was written. Translations of the document are the responsibility of the sponsor involved.

PART III: CONSUMER INFORMATION

PANTOLOC M™ (pantoprazole magnesium)

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

ABOUT THIS MEDICATION

What the medication is used for:

PANTOLOC M is used to treat acid-related stomach problems such as stomach ulcers (also known as gastric ulcers), duodenal ulcers (including ulcers that are associated with a bacterium called *Helicobacter pylori*), reflux esophagitis (a severe form of heartburn), and symptoms of gastro-esophageal reflux disease (heartburn and acid regurgitation).

What it does:

PANTOLOC M™ works by reducing the amount of acid made in your stomach.

When it should not be used:

You should not take PANTOLOC M™ if you think you might be allergic to any of the ingredients.

What the medicinal ingredient is:

pantoprazole magnesium

What the important nonmedicinal ingredients are:

Anhydrous Sodium Carbonate, Mannitol, Crospovidone, Povidone, Calcium Stearate, Hypromellose, Titanium Dioxide, Ferric Oxide, Propylene Glycol, Poly (ethylacrylate, methacrylic acid), Triethyl Citrate

What dosage forms it comes in:

enteric-coated* tablet, 40 mg

(*coated to prevent breakdown in the stomach)

WARNINGS AND PRECAUTIONS

BEFORE you use PANTOLOC M™ you should tell your doctor:

- about all health problems you have now or have had in the past;
- about all other medicines you take, including ones you can get without a prescription;
- if you are allergic to pantoprazole or to the "non-medicinal" ingredients which are present in PANTOLOC M™;
- if you are pregnant, plan to become pregnant or are breastfeeding.
- If you have a history of liver disease.
- If you have any kidney problems.

The safety and efficacy of PANTOLOC M™ has not been established in children.

INTERACTIONS WITH THIS MEDICATION

Drugs that may interact with PANTOLOC M™: There is no known drug interaction with pantoprazole magnesium.

PROPER USE OF THIS MEDICATION

Your doctor will have explained why you need to be treated with PANTOLOC M™ and will have told you what dose to take. Follow your doctor's directions carefully as they may be different from the information provided in this leaflet.

Usual dose:

Your doctor has recommended you take PANTOLOC M™ tablets for a specific number of weeks. Keep taking PANTOLOC M™ until you have finished all your tablets, as recommended by your doctor. Do not stop even when you start to feel better. If you stop taking PANTOLOC M™ too soon, your symptoms may return.

PANTOLOC M™ should be taken in the morning, with or without food. Swallow the tablet(s) whole, with water. Do not crush or chew the tablet(s).

PANTOLOC M™ may be used in combination with two antibiotics to treat ulcers associated with *Helicobacter pylori*. Doses of PANTOLOC M™ and each of the antibiotics should be taken twice a day, or as prescribed by your doctor.

Overdose:

If you or someone you know takes a lot more than the recommended dose (an overdose) you should contact a doctor or pharmacist immediately or go to the nearest emergency department.

Missed Dose:

If you forget to take one dose of PANTOLOC M™, take a tablet as soon as you remember, unless it is almost time for your next dose. If it is, do not take the missed tablet at all. Never double-up on a dose to make up for the one you have missed, just go back to your regular schedule.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like any medication, PANTOLOC M™ may cause side effects in some people. When side effects have been reported, they have been generally mild and did not last a long time. Headache and diarrhea are the most common side effects; less often rash, itchiness and dizziness can occur. If any of these become troublesome, consult your doctor. If you experience any unusual or unexpected symptoms while using PANTOLOC M™, consult your doctor.

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

HOW TO STORE IT

Keep your tablets at room temperature (15 to 30°C) and in a safe place, where children cannot reach them.

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: cadtmp@hc-sc.gc.ca

By regular mail:

National AR Centre

Marketed Health Products Safety and Effectiveness

Information Division

Marketed Health Products Directorate

Tunney's Pasture, AL 0701C

Ottawa ON K1A 0K9

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

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be found at <http://www.altanapharma.ca>, or by contacting the sponsor, ALTANA Pharma Inc., at: 1-866-295-4636

This leaflet was prepared by ALTANA Pharma Inc.

Last revised: <April 2005>.