

# INFORMATION FOR THE PATIENT

## APO-MISOPROSTOL

### Misoprostol Tablets

#### **WHAT IS APO-MISOPROSTOL?**

APO-MISOPROSTOL (also called misoprostol) is approved in Canada for the treatment and primary prevention of gastroduodenal damage caused by arthritis medicines called NSAIDs. Gastroduodenal damage refers to damage in either the stomach or duodenum. Your duodenum is the small portion of the intestine that is immediately adjacent to the stomach.

#### **WHAT IS A NSAID?**

NSAID is an abbreviation for "non-steroidal anti-inflammatory drug". "Non-steroidal" means that this type of medicine does not contain steroids, such as cortisone or prednisone. "Anti-inflammatory" means that the medicine works by decreasing inflammation.

NSAID medicines are commonly prescribed to treat the pain and inflammation of arthritis and certain muscle conditions. While NSAIDs have many benefits, unfortunately they can cause stomach and gastrointestinal ulcers in some people. These ulcers often appear without any pain or warning symptoms.

#### **WHY DO NSAIDs SOMETIMES CAUSE ULCERS?**

Your body contains a mucous layer on the inside of the stomach and intestine to protect it from stomach acids and digestive juices needed to digest food. The body produces natural substances called "prostaglandins" to keep this layer intact.

NSAIDs are believed to treat arthritis by lowering the amount of "prostaglandins". This has a good effect on the joints by helping to decrease the pain, redness and swelling of arthritis. Unfortunately, NSAIDs can also thin the protective mucous layer inside the stomach. The stomach can then become more prone to developing ulcers.

#### **WHO IS AT RISK?**

You may be at higher risk of developing a NSAID-ulcer if you must continue taking arthritis medicine and you:

- are older than 60 years of age
- have had stomach upset in the past while taking NSAID medicines
- have had a stomach ulcer(s)
- are taking high doses of NSAIDs or multiple dosages of NSAIDs including taking Over-The-Counter NSAIDs such as A.S.A. or ibuprofen
- are taking certain other medicines such as corticosteroids or anticoagulants that are known to either damage the stomach or worsen the outcome of a damaged stomach
- have other serious medical conditions or are in poor health
- are severely disabled by an arthritic condition.

In addition, you may be at greater risk in the first three months after starting your NSAID.

#### **HOW DOES APO-MISOPROSTOL WORK?**

APO-MISOPROSTOL is a manufactured prostaglandin similar to the prostaglandins found naturally in your body. APO-MISOPROSTOL replaces the prostaglandins that your body is losing while you are taking the NSAID medicine. In doing this, APO-MISOPROSTOL helps protect your stomach and duodenum.

APO-MISOPROSTOL helps protect your stomach and duodenum from NSAID ulcers in two ways:

- It protects the mucous layer on the inside of your stomach.
- It decreases the amount of acid that may irritate the lining of your stomach and duodenum.

APO-MISOPROSTOL makes it possible for you to continue taking the NSAID medicine for your arthritis by protecting your stomach and duodenum.

APO-MISOPROSTOL is also used to help heal duodenal ulcer.

#### **HOW DO YOU TAKE APO-MISOPROSTOL?**

**DO** Take each dose of APO-MISOPROSTOL immediately after a meal or with food or milk. This will help prevent gastrointestinal disturbances ( e.g. loose stools, diarrhea, and abdominal cramping) that may occur in the first few days of therapy.

**DO** Continue to take APO-MISOPROSTOL if you develop these symptoms. Do not be alarmed. This is part of the effect of the medicine which your body is adjusting to. Keep taking APO-MISOPROSTOL. These symptoms will usually disappear within a few days.

**DO** Call your doctor if these symptoms become bothersome or do not go away within one week.

**DON'T** Do not take antacids that contain magnesium while you are taking APO-MISOPROSTOL. Ask your doctor or pharmacist for help in selecting a suitable antacid.

**DON'T** Do not share APO-MISOPROSTOL with anyone.

**DO** Keep APO-MISOPROSTOL and all other medicines out of the reach of children.

**DON'T** Do not take APO-MISOPROSTOL if you are allergic to prostaglandins.

#### **Special Note for Women of Childbearing Age**

APO-MISOPROSTOL may cause a miscarriage or may otherwise harm the unborn developing baby. Therefore, if you are pregnant, you must not take this drug.

Miscarriages caused by APO-MISOPROSTOL are likely to be incomplete. An incomplete miscarriage may result in very serious medical complications, resulting in hospitalization, surgery and possible infertility.

If you think you are pregnant, you must not take APO-MISOPROSTOL. You should avoid becoming pregnant while you are taking APO-MISOPROSTOL. This means using an effective form of birth control. Stop taking APO-MISOPROSTOL, and contact your doctor immediately if you do become pregnant during APO-MISOPROSTOL therapy.

You should not take APO-MISOPROSTOL if you are nursing because the potential excretion of misoprostol acid could cause diarrhea in nursing infants.

#### **ADULT DOSAGE**

For treatment and prevention of non-steroidal anti-inflammatory drug induced gastroduodenal ulcer: 400 to 800 mcg per day in divided doses. Treatment of duodenal ulcer: 800 mcg daily in two or four equally divided doses. Take after food. Not recommended for patients under 18 years of age.

#### **STORAGE**

Store between 15° and 30°C. Protect from humidity. Keep container closed when not in use.

#### **WHO MANUFACTURES APO-MISOPROSTOL**

Apotex Inc.  
150 Signet Drive  
Weston, Ontario  
M9L 1T9

#### **REMINDERS:**

**This medicine has been prescribed only for you. Do not give it to anybody else.**

***If you require any further information or advise please consult your doctor or pharmacist.***