

IMPORTANT: PLEASE READ

PART III: CONSUMER INFORMATION

^{Pr}**APO-PIROXICAM**
Piroxicam Capsules
Apotex Standard

Read this information each time you refill your prescription in case new information has been added.

This leaflet is part III of a three-part “Product Monograph” published when APO-PIROXICAM 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-PIROXICAM. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:

Your health care provider has prescribed APO-PIROXICAM Capsules for you for symptomatic relief of one or more of the following medical conditions:

- rheumatoid arthritis;
- osteoarthritis (degenerative joint disease);
- ankylosing spondylitis.

What it does:

APO-PIROXICAM (piroxicam) Capsules, as a nonsteroidal anti-inflammatory drug (NSAID), can reduce the chemicals produced by your body, which cause pain and swelling.

APO-PIROXICAM Capsules does NOT cure your illness or prevent it from getting worse. APO-PIROXICAM can only relieve the pain and reduce swelling as long as you continue to take it.

When it should not be used:

DO NOT TAKE APO-PIROXICAM if you have any of the following medical conditions:

- Heart bypass surgery (planning to have or recently had)

- Severe uncontrolled heart failure
- Bleeding in the brain or other bleeding disorder
- Current pregnancy (after 28 weeks of pregnancy)
- Currently breastfeeding (or planning to breastfeed)
- Allergy to ASA (Acetylsalicylic Acid) or other NSAIDs (Nonsteroidal Anti-Inflammatory Drugs)
- Ulcer (active)
- Bleeding from the stomach or gut (active)
- Inflammatory bowel disease (Crohn’s Disease or Ulcerative Colitis)
- Liver disease (active or severe)
- Kidney disease (severe or worsening)
- High potassium in the blood
- Allergy to piroxicam or any other component of APO-PIROXICAM capsules.

Patients who took a drug in the same class as APO-PIROXICAM after a type of heart surgery (coronary artery bypass grafting (CABG)) were more likely to have heart attacks, strokes, blood clots in the leg(s) or lung(s), and infections or other complications than those who did NOT take that drug.

APO-PIROXICAM should NOT be used in patients under 16 years of age since the safety and effectiveness have NOT been established.

What the medicinal ingredient is:

Piroxicam

What the important nonmedicinal ingredients are:

Non-medicinal ingredients include: D&C Red #28, FD&C Blue #1, FD&C Red #40, gelatin, lactose, microcrystalline cellulose, sodium lauryl sulfate, sorbitan monolaurate, starch, stearic acid, talc and titanium dioxide.

What dosage forms it comes in:

APO-PIROXICAM is available as capsules of 10 mg and 20 mg.

WARNINGS AND PRECAUTIONS

If you have, or previously had, any of the following medical conditions, see your health care provider to discuss treatment options other than APO-PIROXICAM:

- Heart Attack or Angina
- Stroke or Mini-stroke

- **Loss of Vision**
- **Current Pregnancy (less than 28 weeks)**
- **Congestive Heart Failure**
- **Gastrointestinal conditions such as ulcers, stomach bleeding, obstruction**
- **Kidney problems (i.e. sodium retention) leading to increase blood pressure**

Before taking this medication, tell your health care provider if you have any of the following:

- High blood pressure
- High cholesterol
- Diabetes mellitus or on a low sugar diet
- Atherosclerosis
- Poor circulation to your extremities
- Smoker or ex-smoker
- Kidney disease or urine problems
- Previous ulcer or bleeding from the stomach or gut
- Previous bleeding in the brain
- Bleeding problems
- Family history of allergy to NSAIDs, such as acetylsalicylic acid (ASA), celecoxib, diclofenac, diflunisal, etodolac, fenoprofen, flurbiprofen, ibuprofen, indomethacin, ketoprofen, ketorolac, mefenamic acid, meloxicam, nabumetone, naproxen, oxaprozin, piroxicam, rofecoxib, sulindac, tenoxicam, tiaprofenic acid, tolmetin, or valdecoxib (NOT a complete list)
- Family history of asthma, nasal polyps, long-term swelling of the sinus (chronic sinusitis) or hives
- Any other medical problem.

Also, before taking this medication, tell your health care provider if you are planning to get pregnant.

While taking this medication:

- tell any other doctor, dentist, pharmacist or other health care professional that you see, that you are taking this medication, especially if you are planning to have heart surgery;
- do NOT drink alcoholic beverages while taking this medication because you would be more likely to develop stomach problems;
- fertility may be decreased. The use of APO-PIROXICAM is not recommended in women trying to get pregnant. In women who have difficulty conceiving, stopping APO-PIROXICAM should be considered;
- Check with your doctor if you are not getting any relief or if any problems develop;
- Your regular medical checkups are essential.

INTERACTIONS WITH THIS MEDICATION

Talk to your health care provider and pharmacist if you are taking any other medication (prescription or non-prescription) such as any of the following (NOT a complete list):

- Acetylsalicylic Acid (ASA) or other NSAIDs
 - e.g. ASA, celecoxib, diclofenac, ibuprofen, indomethacin, ketorolac, meloxicam, naproxen
- Antacids
- Antidepressants
 - Selective Serotonin Reuptake Inhibitors (SSRIs)
 - o e.g. citalopram, fluoxetine, paroxetine, sertraline
- Blood pressure medications
 - ACE (angiotensin converting enzyme) inhibitors
 - o e.g. enalapril, lisinopril, perindopril, ramipril
 - ARBs (angiotensin II receptor blockers)
 - o e.g. candesartan, irbesartan, losartan, valsartan
 - Beta-adrenergic blockers
 - o e.g. propranolol
- Blood thinners
 - e.g. warfarin, ASA, clopidogrel
- Cholestyramine
- Cimetidine
- Corticosteroids (including glucocorticoids)
 - e.g. prednisone
- Cyclosporin
- Diuretics
 - e.g. furosemide, hydrochlorothiazide
- Lithium
- Methotrexate
- Oral contraceptives
- Oral hypoglycemics (diabetes medications)
- Tacrolimus

Your health care provider may prescribe low dose ASA (acetylsalicylic acid) as a blood thinner to reduce your risk of having a heart attack or stroke while you are taking APO-PIROXICAM. Take only the amount of ASA prescribed by your health care provider. You are more likely to upset or damage your stomach if you take both APO-PIROXICAM and ASA than if you took APO-PIROXICAM alone.

PROPER USE OF THIS MEDICATION

Usual dose:

Medical Condition	Starting Dose	Maximum Dose (per day)
Rheumatoid Arthritis,	20 mg once daily or 10 mg twice daily. According to therapeutic response, the dose may be reduced to 10 mg once daily.	20 mg
Ankylosing Spondylitis	20 mg once daily or 10 mg twice daily. According to therapeutic response, the dose may be reduced to 10 mg once daily.	20 mg
Osteoarthritis	20 mg once daily or 10 mg twice daily. According to therapeutic response, the dose may be reduced to 10 mg once daily.	20 mg

Take APO-PIROXICAM only as directed by your health care provider. **Do NOT take more of it, do NOT take it more often and do NOT take it for a longer period of time than your health care provider recommended. If possible, you should take the lowest dose of this medication for the shortest time period.** Taking too much APO-PIROXICAM may increase your chances of unwanted and sometimes dangerous side effects, especially if you are elderly, have other diseases or take other medications.

See your health care provider regularly to discuss whether this medicine is working for you and if it is causing you any unwanted effects.

This medication has been prescribed specifically for you. Do NOT give it to anyone else. It may harm them, even if their symptoms seem to be similar to yours.

APO-PIROXICAM is NOT recommended for use in patients under 16 years of age since safety and effectiveness have NOT been established.

APO-PIROXICAM should be taken immediately after a meal or with food or milk.

Missed Dose:

If you take APO-PIROXICAM once a day and if you miss a dose of this medicine and remember within 8 hours of the missed dose, take it right away. If you take APO-PIROXICAM twice a day and if you miss a dose and remember within 2 hours of the missed dose take it right away. Then go back to your regular dosing schedule.

Overdose:

If you take more than the prescribed dose, contact a health care practitioner, hospital emergency department or regional Poison Control Center immediately, even if there are no symptoms.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

APO-PIROXICAM may cause some side effects, especially when used for a long time or in large doses. When these side effects occur, you may require medical attention. Report all symptoms or side effects to your health care provider.

APO-PIROXICAM may cause you to become drowsy or tired. Be careful about driving or participating in activities that require you to be alert. If you become drowsy, dizzy or light-headed after taking APO-PIROXICAM, do NOT drive or operate machinery.

APO-PIROXICAM may cause you to become more sensitive to sunlight. Any exposure to sunlight or sunlamps may cause sunburn, skin blisters, skin rash, redness, itching or discoloration, or vision changes. If you have a reaction from the sun, check with your health care provider.

Check with your health care provider IMMEDIATELY if you develop chills, fever, muscle aches or pains, or other flu-like symptoms, especially if they occur before or together with a skin rash. These symptoms may be the first signs of a SERIOUS ALLERGIC REACTION to this medication.

SERIOUS ADVERSE EFFECTS AND WHAT TO DO ABOUT THEM

Symptom	STOP taking APO-PIROXICAM and get emergency medical attention IMMEDIATELY	STOP taking APO-PIROXICAM and talk to your physician or pharmacist
Bloody or black tarry stools	√	
Shortness of breath, wheezing, any trouble breathing, chest tightness,	√	
Skin rash, hives, swelling or itching	√	
Blurred vision, or any visual disturbance	√	
Any change in the amount or colour of urine (red or brown)	√	

SERIOUS ADVERSE EFFECTS AND WHAT TO DO ABOUT THEM

Any pain or difficulty experienced while urinating		√
Swelling of the feet, lower legs; weight gain		√
Vomiting or persistent indigestion, nausea stomach pain or diarrhea		√
Yellow discoloration of the skin or eyes, with or without itchy skin		√
Malaise, fatigue, loss of appetite		√
Headaches, stiff neck		√
Mental confusion, depression		√
Dizziness, lightheadedness		√
Hearing problems		√

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

HOW TO STORE IT

Store between 15°C and 30°C.

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
Address Locator: 0701D
Ottawa, ON 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

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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