

PART III: CONSUMER INFORMATION

Pr **Mobicox**[®]
(meloxicam) Tablets

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 MOBICOX was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary designed specifically for you to read. It will NOT tell you everything about MOBICOX. See your health care provider and pharmacist regularly and ask them questions about your health and any medications you take.

ABOUT THIS MEDICATION

What the medication is used for:

MOBICOX (meloxicam) belongs to a class of drugs known as nonsteroidal anti-inflammatory drugs (NSAIDs).

Your health care provider has prescribed MOBICOX for you for symptomatic relief of one or more of the following medical conditions:

- rheumatoid arthritis in adults;
- painful osteoarthritis (arthrosis, degenerative joint disease) in adults.

What it does:

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

MOBICOX, as a nonsteroidal anti-inflammatory drug (NSAID), does NOT cure your illness or prevent it from getting worse. MOBICOX only can relieve pain and reduce swelling as long as you continue to take it.

When it should not be used:

DO NOT TAKE MOBICOX if you have, or previously had any of the following medical conditions:

- **Heart bypass surgery (planning to have or recently had);**
- **Severe, uncontrolled heart failure;**
- **Congestive heart failure;**
- **Bleeding in the brain or other bleeding disorders;**
- **Current pregnancy;**
- **Currently breastfeeding (or planning to breastfeed);**
- **Allergy to meloxicam or any other component of MOBICOX (see non-medicinal ingredients below);**
- **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;**
- **Rare hereditary conditions that may be incompatible with the non-medicinal ingredient, lactose.**

Patients who took a drug in the same class as MOBICOX 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.

MOBICOX should NOT be used in patients under 18 years of age since safety and effectiveness have NOT been established.

What the medicinal ingredient is:

Meloxicam

What the non-medicinal ingredients are:

Colloidal anhydrous silica, crospovidone, lactose monohydrate, magnesium stearate, microcrystalline cellulose, povidone K25, sodium citrate

What dosage forms it comes in:

Tablets, 7.5 mg and 15 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 MOBICOX:

- **heart attack or angina**
- **stroke or mini-stroke**
- **loss of vision**
- **current pregnancy**
- **congestive heart failure**

Before taking this medication, tell your health care provider if you have:

- high blood pressure;
- high cholesterol;
- diabetes mellitus or on a low sugar diet;
- on any special diet, such as low sodium;
- atherosclerosis (plaque builds up in the walls of arteries);
- poor circulation to your extremities (hands and feet);
- smoker or ex-smoker;
- kidney disease or urine problems;
- liver disease;
- previous ulcer or bleeding from the stomach or gut;
- previous bleeding in the brain;
- bleeding problem;
- family history of allergy to anti-inflammatory drugs (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 chronic urticaria (hives);
- an intolerance to some sugars (such as lactose).

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

While taking this medication:

- Tell any other physician, 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 MOBICOX is not recommended in women trying to get pregnant. In women who have difficulty conceiving, stopping MOBICOX should be considered.

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, naproxen
- Anti-depressants - Selective Serotonin Reuptake Inhibitors (SSRIs) e.g. citalopram, fluoxetine, paroxetine, sertraline
- Anti-Diabetics e.g. sulphonylureas, meglinides
- Blood pressure medications
 - Angiotensin Converting Enzyme (ACE) Inhibitors e.g. enalapril, lisinopril, perindopril, Ramipril
 - Angiotensin II receptor blockers (ARBs) e.g. candesartan, irbesartan, losartan, valsartan
- Blood thinners e.g. warfarin, ASA, clopidogrel
- Cholestyramine
- Cimetidine
- Corticosteroids (including Glucocorticoids) e.g. prednisone
- Cyclosporine
- Digoxin
- Diuretics e.g. furosemide, hydrochlorothiazide
- Lithium
- Methotrexate
- Oral contraceptives or intrauterine devices
- Tacrolimus
- Pemetrexed

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 MOBICOX. 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 MOBICOX and ASA than if you took MOBICOX alone. Only take ASA if your doctor tells you to.

PROPER USE OF THIS MEDICATION

DOSE:

Medical Condition	Starting Dose	Maximum Dose (per day)
Symptomatic treatment of rheumatoid arthritis in adults	15 mg	15 mg 7.5 mg for dialysis patients
Painful osteoarthritis (arthrosis, degenerative joint disease) in adults	7.5 mg	15 mg 7.5 mg for dialysis patients

Take MOBICOX 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 MOBICOX increases your chances of unwanted and sometimes dangerous side effects, especially if you are elderly, have other diseases or take other medications.

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.

MOBICOX is NOT recommended for use in patients under 18 years of age since safety and effectiveness have NOT been established.

MOBICOX tablets may be taken with or without food.

Missed Dose:

You should take MOBICOX as your doctor has prescribed. However, if you miss a dose, just resume your usual schedule the following day. Do not take an extra dose.

Overdose:

If you take more than the prescribed dose, contact your health care provider or your local Poison Control Centre immediately.

Along with its beneficial effects, MOBICOX may cause some side effects especially when used for a long time or in large doses. When they do occur, they may require medical attention. Report all symptoms or side effects to your health care provider.

MOBICOX 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 MOBICOX, do NOT drive or operate machinery.

MOBICOX 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 discolouration, 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.

Other side effects may include:

- low red blood cell count (anaemia), decrease in certain white blood cells (leucopenia), low platelet count (thrombocytopenia) and cytopenia (deficiency of some cellular elements of the blood) if taken with drugs like methotrexate;
- sleepiness, drowsiness and headache;
- discharge with itching of the eyes and crusty eyelids, swollen runny eyes;
- sore mouth, mouth ulcers and cold sores (stomatitis);
- weight increased, weight decreased;
- ringing of the ears (tinnitus), vertigo;
- feeling your heartbeat (palpitations);
- blood pressure increase, flushing;
- an uncomfortable feeling in the stomach or belching after eating and indigestion, constipation and flatulence;
- diarrhea;
- abnormal liver function tests (e.g., raised transaminases or bilirubin) and kidney (renal) function tests (e.g., increased serum creatinine and/or serum urea);
- itching, redness of skin, rash, hives (urticaria), severe skin reactions (erythema multiforme);
- ankle swelling (edema);
- inability to become pregnant, delayed ovulation.

MOBICOX can cause abnormal blood test results. They may indicate problems with your kidneys (increased creatinine and/or urea) or liver (increased liver enzymes). They may show low red blood cells (anaemia); decreased white blood cells or low platelet count (may lead to unexpected bleeding). Your doctor will decide when to perform blood tests and will

interpret the results.

SERIOUS SIDE EFFECTS AND WHAT TO DO ABOUT THEM		
Symptom / effect	STOP taking MOBICOX and seek immediate emergency medical attention	STOP taking MOBICOX and talk to your physician or pharmacist
Bloody or black tarry stools and abdominal pain (gastroduodenal ulcer, colitis, gastritis, intestinal haemorrhage, gastroduodenal perforation (which may be fatal))	✓	
Shortness of breath, wheezing, any trouble in breathing, or tightness in the chest	✓	
Allergic reactions, such as: skin rash, hives or swelling, itching, chills, fever, muscle aches and pains, or other flu-like symptoms	✓	
Rapid swelling of face, lips, tongue (angioedema)	✓	
Blurred vision, or any visual disturbance	✓	
Any change in the amount or colour of your urine (red or brown)	✓	
Any pain or difficulty experienced while urinating		✓
Kidney impairment including acute kidney failure (little or no urine)		✓
Swelling of the feet, lower legs, weight gain		✓
Vomiting or persistent indigestion, nausea, stomach pain or diarrhea		✓
Yellow discolouration of the skin or eyes, with or without itchy skin		✓
Malaise, fatigue, loss of appetite		✓
Headaches, stiff neck		✓
Mental confusion, altered mood, depression		✓
Dizziness, lightheadedness		✓

SERIOUS SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Symptom / effect	STOP taking MOBICOX and seek immediate emergency medical attention	STOP taking MOBICOX and talk to your physician or pharmacist
Hearing problems		✓
Stevens-Johnson syndrome (symptoms may include: fever, sore throat, and fatigue followed by ulcers and other lesions to appear in the mouth and on lips but also in the genital and anal regions)	✓	
Toxic epidermal necrolysis (symptoms may include: starts with painful red areas on skin, then large blisters and ends with peeling of layers of skin. This is accompanied by fever and chills, aching muscles and generally feeling unwell.)	✓	✓
Skin eruptions, severe hives and blisters (dermatitis bullous)	✓	
Inflammation of the liver (symptoms may include: nausea, abdominal pain, aches, tiredness, lack of appetite and a general ill feeling or “flu-like” symptoms)	✓	✓

This is NOT a complete list of side effects. For any unexpected effects while taking MOBICOX, contact your health care provider or pharmacist immediately, so that these effects may be properly addressed.

HOW TO STORE IT

Store at room temperature (15-30°C). Store in a dry place.

Do NOT keep outdated medicine or medicine no longer needed. Any outdated or unused medicine should be returned to your pharmacist. **Keep out of reach of children.**

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 0701E
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 the side effect, please contact your health care provider before notifying Canada Vigilance. 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 at:

<http://www.boehringer-ingelheim.ca>

or by contacting the sponsor, Boehringer Ingelheim (Canada) Ltd., at: 1-800- 263-5103, ext. 84633 (Medical Information).

Please visit our website to see if more up-to-date information has been posted.

This leaflet was prepared by Boehringer Ingelheim (Canada) Ltd.

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