

PART III: CONSUMER INFORMATION

Robax Platinum®
Methocarbamol 500 mg, Ibuprofen 200 mg Caplets

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

ABOUT THIS MEDICATIONWhat the medication is used for:

For effective relief of pain associated with muscle spasm such as back pain, tense neck, muscles, strains and sprains.

What it does:

Pain reliever and Muscle Relaxant.

When it should not be used:

Do not take Robax Platinum if you have or are:

- peptic ulcer disease or gastrointestinal bleeding or any other active inflammatory disease of the gastrointestinal tract (e.g. colitis, Crohn's disease),
- taking acetylsalicylic acid (ASA) or any other non-steroidal anti-inflammatory medication including any other ibuprofen product,
- allergic/hypersensitive to ibuprofen or other non-steroidal anti-inflammatory drugs (NSAIDs), ASA or other salicylates, methocarbamol or to any ingredient in the formulation or component of the container, or any of Robax Platinum caplets ingredients (Refer to the nonmedicinal ingredients on outer carton or composition section),
- nasal polyps (swelling of the inside of the nose), or allergic manifestations such as asthma, anaphylaxis (sudden severe life threatening allergic reaction), urticaria/hives, rhinitis (stuffed or runny nose that may be due to allergies), skin rash or other allergic symptoms,
- dehydrated (significant fluid loss) due to vomiting, diarrhea or lack of fluid intake,
- serious liver or kidney disease,
- Systemic Lupus Erythematosus,
- or if you are pregnant or nursing.

What the medicinal ingredient is:

Methocarbamol and ibuprofen.

What the important nonmedicinal ingredients are:

Colloidal silicon dioxide, copovidone, FD&C Blue No. 2, ferric oxide (red), hypromellose, methyl cellulose, microcrystalline cellulose, polyethylene glycol, sodium starch glycolate, stearic acid.

What dosage forms it comes in:

Each caplet contains methocarbamol 500 mg and ibuprofen 200 mg.

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions

- Caution in those with heart failure, high blood pressure or other conditions predisposing to fluid retention.
- Caution in those prone to gastrointestinal tract irritation, diverticulosis, or other inflammatory disease of the gastrointestinal tract such as ulcerative colitis or Crohn's disease.
- Caution in those at risk of kidney or liver problems, those taking diuretics and the elderly.
- Stop use immediately if you have difficulty or pain when urinating.

BEFORE you use Robax Platinum talk to your doctor or pharmacist if:

- you have diabetes, high blood pressure, heart or thyroid disease, asthma, kidney or liver disease, glaucoma, blood clotting disorder (such as hemophilia), any other serious disease, are under doctor's care for any serious condition, or are taking any other drug including over the counter drugs.

May cause drowsiness or dizziness. Exercise caution in operating machinery or motor vehicles. Avoid alcohol. Use with caution in the elderly.

INTERACTIONS WITH THIS MEDICATION

Do not use this product if you are taking ASA.

Drugs that may interact with Robax Platinum include: acetaminophen, anticoagulants (blood thinners), digoxin, oral antidiabetic agents and insulin, diuretics, methotrexate, lithium, protein-bound drugs including probenecid, thyroxine, antibiotics (e.g. cyclosporine), phenytoin, corticosteroids or benzodiazepenes, other NSAIDs, or medications for high blood pressure. Tell your doctor or pharmacist what prescription drugs you are taking or plan to take.

PROPER USE OF THIS MEDICATIONUsual dose:

Adults and children over 12: Take 1 or 2 caplets every four to six hours as needed. Do not exceed 6 caplets in 24 hours, unless directed by a physician. Consult your physician if symptoms persist for more than 5 days.

Overdose:

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

Missed Dose:

Continue to take 1-2 tablets every 4-6 hours as needed after a missed dose. Do not take twice the recommended dose following a missed dose.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Robax Platinum may occasionally produce unwanted side effects, such as heartburn, constipation, nausea, bloating, nervousness or sleeplessness.

Stop use and contact a doctor or pharmacist if these symptoms worsen or persist.

The risk of having side effects may be decreased by using the smallest dose for the shortest duration of time.

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:

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- \$ 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 0701D
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 side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect		Talk with your doctor or pharmacist		Seek immediate emergency medical assistance
		Only if severe	In all cases	
Uncommon	Symptoms of severe allergic reaction (anaphylaxis), including: rash, severe itching/redness, blisters, swelling, or trouble breathing			T
	Blood in vomit, bloody or black stools			T
	Abdominal pain, vomiting, diarrhea		T	
	ringing or buzzing in the ears / dizziness		T	
	Change in vision including: blurred or diminished vision		T	
	Fluid retention		T	

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

HOW TO STORE IT

Store at room temperature (15-30°C). Protect from light.

Keep out of reach of children. This package contains enough medicine to seriously harm a child.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be found by contacting the sponsor, Pfizer Consumer Healthcare, a division of Pfizer Canada Inc., Mississauga, ON L4Z 3M6 at: 1-800-275-9938 or www.backrelief.com.

This leaflet was prepared by Pfizer Consumer Healthcare, a division of Pfizer Canada Inc.

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