

Fenoprofen Calcium



A Nonsteroidal Option That Helps With Inflammation

Where arthritis pain and discomfort meet effective relief

Fenoprofen Calcium Capsules, USP 300 mg

NDC: 85437-502-10

INDICATIONS:

- Relief of mild to moderate pain in adults
- Relief of the signs and symptoms of rheumatoid arthritis
- Relief of the signs and symptoms of osteoarthritis

WARNINGS AND PRECAUTIONS:

Hepatotoxicity: Inform patients of warning signs and symptoms of hepatotoxicity. Discontinue if abnormal liver tests persist or worsen or if clinical signs and symptoms of liver disease develop.

Hypertension: Patients taking some antihypertensive medications may have an impaired response to these therapies when taking NSAIDs. Monitor blood pressure.

Heart Failure and Edema: Avoid use of fenoprofen calcium in patients with severe heart failure unless benefits are expected to outweigh the risk of worsening heart failure.

Renal Toxicity: Monitor renal function in patients with renal or hepatic impairment, heart failure, dehydration, or hypovolemia. Avoid use of fenoprofen calcium in patients with advanced renal disease unless benefits are expected to outweigh risk of worsening renal function.

Anaphylactic Reactions: Seek emergency help if an anaphylactic reaction occurs.

For full Prescribing Information,
see attached Product Insert.

You are encouraged to report negative side effects of prescription
drugs to the FDA. Visit [fda.gov/medwatch](https://www.fda.gov/medwatch) or call 1-800-FDA-1088.

Fenoprofen Calcium 300 mg may offer the following benefits for patients living with inflammation:



- Long-lasting pain relief
- Arthritis symptom relief
- Reduction in pain intensity

WARNINGS AND PRECAUTIONS:

Exacerbation of Asthma Related to Aspirin Sensitivity:

Fenoprofen calcium is contraindicated in patients with aspirin-sensitive asthma. Monitor patients with preexisting asthma (without aspirin sensitivity).

Serious Skin Reactions: Discontinue fenoprofen calcium at first appearance of skin rash or other signs of hypersensitivity.

Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS): Discontinue and evaluate clinically.

Fetal Toxicity: Limit use of NSAIDs, including fenoprofen calcium, between about 20 to 30 weeks in pregnancy due to the risk of oligohydramnios/fetal renal dysfunction. Avoid use of NSAIDs in women at about 30 weeks gestation and later in pregnancy due to the risks of oligohydramnios/fetal renal dysfunction and premature closure of the fetal ductus arteriosus.

Hematologic Toxicity: Monitor hemoglobin or hematocrit in patients with any signs or symptoms of anemia.

ADVERSE REACTIONS:

Most common adverse reactions (incidence $\geq 5\%$) are dyspepsia, headache, somnolence, nausea, dizziness, constipation, nervousness, asthenia, and peripheral edema.

HOW TO WRITE:

Fenoprofen Calcium

Take 1-2 capsules by mouth three times daily as needed.

☐ 300 mg

Dispense as written.

Drugs that Interfere with Hemostasis (e.g., warfarin, aspirin, SSRIs/SNRIs): Monitor patients for bleeding who are concomitantly taking fenoprofen with drugs that interfere with hemostasis. Concomitant use of Fenoprofen Calcium and analgesic doses of aspirin is not generally recommended.

ACE Inhibitors, Angiotensin Receptor Blockers (ARBs), or Beta-Blockers: Concomitant use with fenoprofen may diminish the antihypertensive effect of these drugs. Monitor blood pressure.

ACE Inhibitors and ARBs: Concomitant use with fenoprofen in elderly, volume depleted, or those with renal impairment may result in deterioration of renal function. In such high-risk patients, monitor for signs of worsening renal function.

Diuretics: NSAIDs can reduce the natriuretic effect of furosemide and thiazide diuretics. Monitor patients to assure diuretic efficacy including antihypertensive effects.

Digoxin: Concomitant use with fenoprofen can increase serum concentration and prolong the half-life of digoxin. Monitor serum digoxin levels.



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WARNING: RISK OF SERIOUS CARDIOVASCULAR AND GASTROINTESTINAL EVENTS

See full prescribing information for complete boxed warning

- **Non-Steroidal Anti-Inflammatory drugs (NSAIDs) cause an increased risk of serious cardiovascular thrombotic events, including myocardial infarction and stroke, which can be fatal. This risk may occur early in treatment and may increase with duration of use.**
- **Fenoprofen Calcium is contraindicated in the setting of coronary artery bypass graft (CABG) surgery.**
- **NSAIDs cause an increased risk of serious gastrointestinal (GI) adverse events including bleeding, ulceration, and perforation of stomach or intestines, which can be fatal. These events can occur at any time during use and without warning symptoms. Elderly patients and patients with a prior history of peptic ulcer disease and/or GI bleeding are at greater risk for serious GI events.**