

FENOPROFEN 400 mg



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INDICATIONS AND USAGE:

Fenopropfen calcium is a nonsteroidal anti-inflammatory drug indicated for:

- 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.

NDC: 71993-0308-90

DOSAGE:

- Use the lowest effective dosage for shortest duration consistent with individual patient treatment goals.
- Analgesia: For the treatment of mild to moderate pain, the recommended dosage is 200 mg given orally every 4 to 6 hours, as needed.
- Rheumatoid Arthritis and Osteoarthritis: For the relief of signs and symptoms of rheumatoid arthritis or osteoarthritis the recommended dose is 400 to 600 mg given orally, 3 or 4 times a day. The dose should be tailored to the needs of the patient and may be increased or decreased depending on the severity of the symptoms. Total daily dosage should not exceed 3,200 mg.

CONTRAINDICATIONS:

- Known hypersensitivity to Fenopropfen or any components of the drug product.
- History of asthma, urticaria, or other allergic-type reactions after taking aspirin or other NSAIDs
- In the setting of CABG surgery.

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 impaired response to these therapies when taking NSAIDs. Monitor blood pressure
- Heart Failure and Edema: Avoid use of Fenopropfen calcium in patients with severe heart failure unless benefits are expected to outweigh 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 Fenopropfen 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.
- Exacerbation of Asthma Related to Aspirin Sensitivity: Fenopropfen calcium is contraindicated in patients with aspirin-sensitive asthma. Monitor patients with preexisting asthma (without aspirin sensitivity).
- Serious Skin Reactions: Discontinue Fenopropfen 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 Fenopropfen 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.

Scan barcode for more information on Fenopropfen.

