

Fenovar™

NDC 72835-202-02

Contents:

Diclofenac Sodium 1.5% (150mL)
Muscle Rub Pain Relieving Cream (85gm)

Typical Prescribing Directions:

Apply 40 drops of Diclofenac to affected area(s) 4 times daily.
Use Muscle Rub cream 3-4 times daily.



Indicated For:

The treatment of signs and symptoms of osteoarthritis of the knee(s)

Contraindications:

- Known hypersensitivity (e.g., anaphylactic reactions and serious skin reactions) to diclofenac, sodium, menthol, methyl salicylate, or any components of the drug product
- History of asthma, urticaria, or other allergic-type reactions after taking aspirin or other NSAIDs. Severe, sometimes fatal, anaphylactic reactions to NSAIDs have been reported in such patients

Warnings:

RISK OF SERIOUS CARDIOVASCULAR AND GASTROINTESTINAL EVENTS

Cardiovascular Thrombotic Events

- Nonsteroidal 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.
- Diclofenac sodium topical solution is contraindicated in the setting of coronary artery bypass graft (CABG) surgery.

Gastrointestinal Bleeding, Ulceration, and Perforation

- NSAIDs cause an increased risk of serious gastrointestinal (GI) adverse events including bleeding, ulceration, and perforation of the 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.

