

# Inflatherm™

**NDC 72835-701-02**



## Contents:

- Diclofenac Sodium Tablets 75 mg (60 count)
- Menthol 3%, Camphor 3% Roll-On Gel (3oz)

## Indicated For:

- Relief of the signs and symptoms of osteoarthritis
- Relief of the signs and symptoms of rheumatoid arthritis
- Acute or long-term use in the relief of signs and symptoms of ankylosing spondylitis

## Typical Prescribing Directions:

Take 1 tablet twice daily. Apply Roll-On gel 3-4 times daily as needed.

## Contraindications:

- Known hypersensitivity (e.g., anaphylactic reactions and serious skin reactions) to diclofenac, sodium, menthol, camphor, 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:

### WARNING: 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.