



DICLOFENAC SODIUM TOPICAL SOLUTION 1.5% (Pennsaid®) UTILIZATION MANAGEMENT CRITERIA

DRUG CLASS:	Topical Non-Steroidal Anti-Inflammatory Drug (NSAID)
Generic (Brand) Name:	Diclofenac topical solution 1.5% (Pennsaid 150 ml bottle)

FDA-APPROVED INDICATIONS:

- Pennsaid is indicated for the treatment of signs and symptoms of osteoarthritis of the knee

COVERAGE AUTHORIZATION CRITERIA for diclofenac solution (Pennsaid):

Diclofenac solution (Pennsaid) is covered for the following conditions:

- Osteoarthritis of the knee after failure of an adequate one-week trial of therapeutic doses of an oral NSAID for this condition, or intolerable side effects or contraindications to oral NSAIDs, or patient at high risk of gastric bleeding with oral NSAIDs*.
- Osteoarthritis of the knee in a patient who cannot swallow solid oral dosage forms and is not currently taking any solid oral dosage form.

Diclofenac solution (Pennsaid) is not covered for the following conditions:

- Used concurrently with an oral NSAID (includes COX-2 inhibitors) prescribed for the same condition.

*Patients at high risk of gastric bleeding include:

Age 60 years or greater; history of peptic ulcer disease or ulcer/GI bleeding related to NSAIDs; current regimen includes anticoagulant, prescription antiplatelet drug, corticosteroid or DMARD (disease-modifying and anti-rheumatic drug) therapy; or hereditary or acquired coagulation defect (e.g., hemophilia, Von Willebrand's disease, protein C or S deficiency, thrombocytopenia or chronic renal failure).

BOXED WARNING: CARDIOVASCULAR AND GASTROINTESTINAL RISK

Cardiovascular Risk

- Nonsteroidal anti-inflammatory drugs (NSAIDs) may cause an increased risk of serious cardiovascular thrombotic events, myocardial infarction, and stroke, which can be fatal. Patients with cardiovascular disease or risk factors for cardiovascular disease may be at greater risk.
- Pennsaid is contraindicated for the treatment of perioperative pain in the setting of coronary artery bypass graft (CABG) surgery.

Gastrointestinal Risk

- NSAIDs, including Pennsaid, cause an increased risk of serious gastrointestinal 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 are at greater risk for serious gastrointestinal events.

DOSAGE:

For the relief of the signs and symptoms of osteoarthritis of the knee(s), the recommended dose is 40 drops on each painful knee, 4 times a day.

- Apply Pennsaid to clean, dry skin.
- Dispense Pennsaid 10 drops at a time either directly onto the knee or first into the hand and then onto the knee. Spread Pennsaid evenly around front, back and sides of the knee. Repeat this procedure until 40 drops have been applied and the knee is completely covered with solution.
- Wash hands completely after administering the product.
- Wait until the area is completely dry before covering with clothing or applying sunscreen, insect repellent, cosmetics, topical medications, or other substances.

REFERENCES:

Diclofenac sodium (Pennsaid) topical solution. Product Information. Covidien AG. 2010.
http://www.penssaid.com/files/PENNSAID_Prescribing_Information.pdf