



DICLOFENAC EPOLAMINE PATCH 1.3% (FLECTOR[®] PATCH) UTILIZATION MANAGEMENT CRITERIA

DRUG CLASS:	Topical Non-Steroidal Anti-Inflammatory Drug (NSAID)
Generic (Brand) Name:	Diclofenac epolamine patch 1.3% (Flector Patch) 180 mg per patch (10x14 cm each) 5 patches per resealable envelope

FDA-APPROVED INDICATIONS:
Pain: Topical treatment of acute pain due to minor strains, sprains and contusions.

COVERAGE AUTHORIZATION CRITERIA for diclofenac patch (Flector Patch):

Diclofenac patch (Flector Patch) is covered for the following conditions:

- Relief of acute pain due to minor strains, sprains and contusions 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*.
- Relief of pain due to minor strains, sprains and contusions in a patient who cannot swallow solid oral dosage forms and is not currently taking any solid oral dosage form.

Diclofenac patch (Flector Patch) 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. This risk may increase with duration of use. Patients with cardiovascular disease or risk factors for cardiovascular disease may be at greater risk.
- Flector Patch is contraindicated in the peri-operative setting of coronary artery bypass graft (CABG) surgery.

Gastrointestinal Risk

- NSAIDs 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:

Adults: Apply one patch to the most painful area twice a day. Apply to intact skin. Do not wear Flector Patch when bathing or showering.

REFERENCES:

Drug Facts and Comparisons eAnswers. Wolters Kluwer. Accessed March 2011.

Flector Patch. DRUGDEX Evaluations. Micromedex 2.0. Thomson Reuters. March 2011.

Flector Patch ® (diclofenac patch 1.3%) prescribing information. King Pharmaceuticals. Bristol, TN. March 2011.