

# New Drug Information

FROM THE EDITORS OF THE **PAPR**

## **PRODUCT:** Flector Patch

**COMPANY:** Alpharma

**PHARMACOLOGIC CLASS:** Topical analgesic (NSAID)

**ACTIVE INGREDIENTS:** Diclofenac epolamine 180mg; per patch.

**INDICATION:** Topical treatment of acute pain due to minor strains, sprains, and contusions.

**PHARMACOLOGY:** Flector is a topical patch that contains 1.3% of diclofenac epolamine, a nonsteroidal anti-inflammatory drug (NSAID). It measures approximately 10×14 cm. When applied to intact skin, it provides local analgesia as the drug is released into the skin. Although the exact mechanism by which NSAIDs alleviate pain has not been established, their ability to inhibit the activity of various prostaglandins may play a role.

Following application of a patch to the upper inner arm, peak plasma levels of diclofenac were noted 10–20 hours later. Diclofenac is highly protein-bound; it is eliminated by both renal and hepatic mechanisms.

**CLINICAL TRIALS:** The efficacy of Flector Patch in alleviating acute pain was demonstrated in two studies in patients with minor sprains, strains, and contusions. Patients were randomly assigned to receive either the Flector Patch or a patch that did not contain the active ingredient. In the first study, patients with ankle sprains were treated once daily for 1 week. In the second study, patients with sprains, strains, and contusions were treated twice daily for up to 2 weeks. Patients treated with the Flector Patch were found to have experienced a greater reduction in pain as compared to those randomized to placebo patch.

**ADULTS:** Use lowest effective dose for shortest possible duration. Apply 1 patch to clean, dry, intact skin on most painful area twice daily. May tape edges down if patch begins to peel off. Wash hands after application. Remove during bathing/showering.

**CHILDREN:** Not recommended.

**CONTRAINDICATIONS:** Aspirin triad/allergy. Perioperative pain for coronary artery bypass graft (CABG). Nonintact or damaged skin (eg, dermatitis, eczema, burns, wounds, lesions).

**PRECAUTIONS:** Advanced renal disease: not recommended. History of ulcer disease or GI bleed, or risks thereof (eg, concomitant corticosteroids, anticoagulants, smoking, alcohol use, prolonged NSAID therapy). Cardiovascular disease or risk. Hypertension. Heart failure. Fluid retention. Impaired renal or liver function. Monitor blood pressure and for thrombotic and GI events. Not a substitute for corticosteroids. Avoid eyes, mucosa. Handle and dispose of properly. Elderly (monitor renal function). Debilitated. Pregnancy (Cat.C; avoid in late pregnancy). Labor & delivery. Nursing mothers: not recommended.

**INTERACTIONS:** Avoid concomitant aspirin. May potentiate lithium, methotrexate, warfarin. May antagonize antihypertensive (eg, ACE inhibitors). Concomitant diuretics, ACE inhibitors: increased risk of renal decompensation.

**ADVERSE REACTIONS:** Skin reactions (eg, burning, dermatitis, pruritus), GI events (eg, nausea, dysgeusia, dyspepsia), headache, paresthesia, somno-

lence. Discontinue if rash or hepatic reaction occurs. See literature re: risk of cardiovascular events, Stevens-Johnson syndrome, toxic epidermal necrolysis, GI ulcer/bleed.

**HOW SUPPLIED:** Patch–30

## **Facts about acute pain in Americans**

- **In a survey** of 1,484 American adults conducted by the National Pain Foundation in December 2007,
  - 72% of respondents reported suffering from some type of pain in the previous 12 months,
  - 27% experienced acute pain in the past year, and
  - 42% were experiencing pain on the day of the survey.
- **Respondents also reported** that pain disrupted their ability to
  - participate in recreational activities (65%),
  - leave the house to run errands (46%),
  - take care of their homes (59%), and
  - take care of themselves and family members (41%).
- **Because of pain**, 22% of respondents reported missing at least one day of work. On the days they did go to work, almost half (48%) reported lower productivity.
- **Seventy percent** of those with acute pain did not see a health care professional. Even among those who did seek care, 81% of respondents and 71% of those with acute pain delayed going, hoping to deal with pain on their own.
- **Finally**, 86% of the survey respondents believed that aches and pains were a normal part of aging, and 26% did not understand that if left untreated, acute pain can lead to chronic pain.

**Data from** The National Pain Foundation. Survey fast facts: treating America's acute pain. [www.nationalpainfoundation.org/MyResearch/PainSurveyFactSheet.pdf](http://www.nationalpainfoundation.org/MyResearch/PainSurveyFactSheet.pdf). Accessed April 7, 2008.



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