



## Flector<sup>®</sup> (diclofenac epolamine) – Expanded indication and first-time generic (authorized generic)

- On March 1, 2019, the FDA announced the approval of [Flector \(diclofenac epolamine\)](#), for the topical treatment of acute pain due to minor strains, sprains, and contusions in adults and pediatric patients 6 years and older.
  - Previously, Flector was only approved for the same indication in adult patients.
  - In addition, Greenstone and [Teva launched](#) authorized generic versions of Flector 1.3% topical system.
- Topical diclofenac is also available generically as [transdermal solution 1.5%](#), [transdermal gel 1%](#), and [transdermal gel 3%](#), and as brand transdermal solution 2% ([Pennsaid<sup>®</sup>](#)).
  - The transdermal solution is indicated for the treatment of signs and symptoms of osteoarthritis of the knee(s).
  - The transdermal gel 1% is indicated for the relief of the pain of osteoarthritis of joints amenable to topical treatment, such as the knees and those of the hands.
  - Transdermal gel 3% is indicated for the topical treatment of actinic keratosis.
  - Pennsaid is indicated for treatment of the pain of osteoarthritis of the knee(s).
- The safety and effectiveness of Flector have been established in pediatric patients 6 years and older based on evidence from adequate and well-controlled studies with Flector in adults, as well as an open-label study in 104 pediatric patients with minor soft tissue injuries.
  - Based on the available data from the pediatric study, the safety profile of Flector topical system in pediatric patients is similar to that in adults.
- Flector carries a boxed warning for risk of serious cardiovascular and gastrointestinal events.
- The most common adverse reactions with Flector use in pediatric patients were headache (9%) and application site pruritus (7%).
- The recommended dose of Flector is one topical system to the most painful area twice a day both in adults and pediatric patients 6 years of age and older.
  - Flector should be used at the lowest effective dosage for the shortest duration consistent with individual patient treatment goals.
  - Flector should not be used in combination with an oral nonsteroidal anti-inflammatory drug unless the benefit outweighs the risk, and periodic laboratory evaluations should be conducted.



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