



Licart™ (diclofenac epolamine) – New drug approval

- On December 19, 2018, the [FDA announced](#) the approval of IBSA Pharma's [Licart \(diclofenac epolamine\)](#), for the topical treatment of acute pain due to minor strains, sprains, and contusions.
- Diclofenac epolamine is also available as the branded patch, [Flector® \(diclofenac epolamine\)](#).
 - Flector carries the same indication as Licart, but must be applied twice daily.
- The efficacy of Licart was based on two placebo- and active-controlled studies in patients with minor sprains, strains, and/or contusions. Patients were randomized to receive Licart, placebo, or Flector once daily for 7 or 14 days. The primary efficacy endpoint was the mean change from baseline in pain on movement to day 3 of treatment.
 - In both studies, Licart demonstrated a statistically significant difference vs. placebo for the reduction in pain on movement at day 3.
 - Conclusions regarding comparative efficacy of Licart vs. Flector cannot be made because Flector was not administered according to its approved twice daily dosing regimen.
- Licart carries a boxed warning for risk of serious cardiovascular and gastrointestinal events.
- Licart is contraindicated in patients with known hypersensitivity to diclofenac or any components of the drug product; history of asthma, urticaria, or allergic-type reactions after taking [aspirin](#) or other nonsteroidal anti-inflammatory drugs (NSAIDs); in the setting of coronary artery bypass graft (CABG) surgery; and use on non-intact or damaged skin.
- Additional warnings and precautions for Licart include hepatotoxicity, hypertension, heart failure and edema, renal toxicity and hyperkalemia, anaphylactic reactions, exacerbation of asthma related to sensitivity, serious skin reactions, premature closure of fetal ductus arteriosus, hematologic toxicity, masking of inflammation and fever, laboratory monitoring, accidental exposure in children, eye exposure, and use in combination with oral NSAIDs.
- The most common adverse reactions of Licart use were application site pruritus and other application site reactions.
- The recommended dose of Licart is to apply the topical system to the most painful area once daily.
 - The lowest effective dosage of Licart for the shortest duration should be used consistent with individual patient treatment goals.
 - Licart should not be worn when bathing or showering.
 - Licart should not be used in combination with an oral NSAID unless the benefit outweighs the risk and periodic laboratory evaluations are conducted.
- IBSA Pharma's launch plans for Licart are pending. Licart will be available as a 1.3% topical system.



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