

Prior Authorization (PA) Quick Reference Guide for Healthcare Providers

INDICATIONS AND USAGE: LICART[®] contains diclofenac epolamine, which is a nonsteroidal anti-inflammatory drug (NSAID), and is indicated for the topical treatment of acute pain due to minor strains, sprains, and contusions in adults and pediatric patients 6 years and older.

Always Required:

- ✓ Diagnosis of acute pain due to minor strains, sprains and contusions
- ✓ ICD-10 Diagnostic Code **G89.11** - Acute pain due to trauma

Additional Supporting Criteria (select appropriate documentation):

- A.** The patient did not receive adequate pain relief when previously treated with oral or topical anti-inflammatory drugs (NSAIDs)
- B.** The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to oral or topical NSAID agents
- C.** Trial and failure of, or contraindication/intolerance to, diclofenac sodium 1% gel (Voltaren OTC)
- D.** Any of the following risk factors for NSAID-induced adverse events:
 - Patient \geq 65 years of age
 - Prior history of peptic, gastric, or duodenal ulcer
 - Prior history of cardiovascular events
 - Bleeding disorder
 - History of NSAID-related ulcer
 - Concurrent use of oral corticosteroids (e.g., prednisone, prednisolone, dexamethasone)
 - Concurrent use of antiplatelet drugs (e.g., aspirin including low dose, clopidogrel, ticagrelor)

Documentation Tips to Support PA Approval

Licart[®]
(diclofenac epolamine) topical system 1.3%

- Document diagnosis: **acute pain** due to minor strains, sprains and contusions
- Add diagnostic code: **G89.11** (add secondary site-specific codes, as applicable)
- Record any prior trials of diclofenac 1% gel (Voltaren OTC), or other topical/oral NSAIDs, including dates, duration, and reason for failure (e.g., lack of efficacy, allergy, intolerable side effects, or drug interaction)
- Contraindications to oral NSAIDs (e.g., GI bleed history, renal impairment, other)
- For reauthorization, include documentation of beneficial response to therapy



FOOT



BACK



NECK



SHOULDER



WRIST



ELBOW



ANKLE



KNEE

IMPORTANT SAFETY INFORMATION

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WARNING: RISK OF SERIOUS CARDIOVASCULAR and GASTROINTESTINAL EVENTS

Cardiovascular Thrombotic Events

- Nonsteroidal anti-inflammatory drugs (NSAIDs) cause an increased risk of serious cardiovascular thrombotic events, including myocardial infarction and stroke, which can be fatal. This risk may occur early in the treatment and may increase with duration of use.
- LICART[®] is contraindicated in the setting of coronary artery bypass graft (CABG) surgery.

Gastrointestinal Bleeding, Ulceration, and Perforation

- NSAIDs cause an increased risk of serious gastrointestinal (GI) 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 and patients with a prior history of peptic ulcer disease and/or GI bleeding are at greater risk for serious GI events.

CONTRAINDICATIONS

LICART[®] is contraindicated in the following patients:

- Known hypersensitivity to diclofenac or any components of the drug product.
- History of asthma, urticaria, or allergic-type reactions after taking aspirin or other NSAIDs.
- In the setting of CABG surgery
- For use on non-intact or damaged skin

WARNINGS AND PRECAUTIONS

- **Hepatotoxicity:** Inform patients of warning signs and symptoms of hepatotoxicity. Discontinue if abnormal liver tests persist or worsen or if clinical signs and symptoms of liver disease develop
- **Hypertension:** Patients taking some antihypertensive medications may have impaired response to these therapies when taking NSAIDs. Monitor blood pressure
- **Heart Failure and Edema:** Avoid use of LICART[®] in patients with severe heart failure unless benefits are expected to outweigh risk of worsening heart failure
- **Renal Toxicity:** Monitor renal function in patients with renal or hepatic impairment, heart failure, dehydration, or hypovolemia. Avoid use of LICART[®] in patients with advanced renal disease unless benefits are expected to outweigh risk of worsening renal function
- **Anaphylactic Reactions:** Seek emergency help if an anaphylactic reaction occurs
- **Exacerbation of Asthma Related to Aspirin Sensitivity:** LICART[®] is contraindicated in patients with aspirin-sensitive asthma. Monitor patients with preexisting asthma (without aspirin sensitivity)
- **Serious Skin Reactions:** Discontinue LICART[®] at first appearance of skin rash or other signs of hypersensitivity
- **Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS):** Discontinue and evaluate clinically
- **Fetal Toxicity:** Limit use of NSAIDs, including LICART, between about 20 to 30 weeks in pregnancy due to the risk of oligohydramnios/fetal renal dysfunction. Avoid use of NSAIDs in women at about 30 weeks gestation and later in pregnancy due to the risks of oligohydramnios/fetal renal dysfunction and premature closure of the fetal ductus arteriosus
- **Hematologic Toxicity:** Monitor hemoglobin or hematocrit in patients with any signs or symptoms of anemia

ADVERSE REACTIONS

Most common adverse reactions for LICART[®] are application site pruritus and other application site reactions.

To report SUSPECTED ADVERSE REACTIONS, contact IBSA Pharma Inc. at 1-800-587-3513 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

References: 1. Licart[®] (diclofenac epolamine) topical system 1.3% [package insert]. Parsippany, NJ: IBSA Pharma; 2020. 2. Coudreuse J-M, de Vathaire F. *Curr Med Res Opin.* 2010;26(9):2221-2228.

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