

# diclofenac epolamine topical system 1.3%



## IMPORTANT SAFETY INFORMATION

### INDICATIONS AND USAGE

Diclofenac epolamine topical system 1.3% 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.

#### **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.
- Diclofenac epolamine topical system 1.3% 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

Diclofenac epolamine topical system 1.3% is contraindicated in the following patients:

- Known hypersensitivity (e.g., anaphylactic reactions and serious skin reactions) to diclofenac or any components of the drug product.
- History of asthma, urticaria, or other allergic-type reactions after taking aspirin or other NSAIDs. Severe, sometimes fatal, anaphylactic reactions to NSAIDs have been reported in such patients in the setting of coronary artery bypass graft (CABG) surgery.
- On non-intact or damaged skin resulting from any etiology, including exudative dermatitis, eczema, infected lesions, burns or wounds.

### 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 diclofenac epolamine topical system 1.3% 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 diclofenac epolamine topical system 1.3% 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:** Diclofenac epolamine topical system 1.3% is contraindicated in patients with aspirin-sensitive asthma. Monitor patients with preexisting asthma (without aspirin sensitivity)
- **Serious Skin Reactions:** Discontinue diclofenac epolamine topical system 1.3% at first appearance of skin rash or other signs of hypersensitivity
- **Premature Closure of Fetal Ductus Arteriosus:** Avoid use in pregnant women starting at 30 weeks gestation
- **Hematologic Toxicity:** Monitor hemoglobin or hematocrit in patients with any signs or symptoms of anemia

### ADVERSE REACTIONS

Most common adverse reactions for diclofenac epolamine topical system 1.3% are application site pruritus and other application site reactions.

**To report SUSPECTED ADVERSE REACTIONS, contact Yaral Pharma Inc. at 866-218-9009 or FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch).**

**Please see Full Prescribing Information, including Boxed Warning, at [www.yaral-pharma.com](http://www.yaral-pharma.com)**

**For more information:** [info@yaral-pharma.com](mailto:info@yaral-pharma.com) • 866-218-9009  
[www.yaral-pharma.com](http://www.yaral-pharma.com)