



DICLOFENAC SODIUM TOPICAL GEL 1% (VOLTAREN® GEL) UTILIZATION MANAGEMENT CRITERIA

DRUG CLASS:	Topical Non-Steroidal Anti-Inflammatory Drug (NSAID)
Generic (Brand) Name:	Diclofenac gel 1% (Voltaren Gel) 100 gm tube

FDA-APPROVED INDICATIONS:

Pain: Relief of the pain of osteoarthritis of joints amenable to topical treatment, such as the knees and those of the hands. Voltaren Gel has not been evaluated for use on the spine, hip, or shoulder.

COVERAGE AUTHORIZATION CRITERIA for diclofenac gel (Voltaren Gel):

Diclofenac gel (Voltaren gel) is covered for the following conditions:

- Pain relief of osteoarthritis involving the elbow, wrist, hand, knee, ankle and/or foot after failure of an adequate one-week trial of therapeutic doses of an oral NSAID for this condition, or intolerable side effects or contraindications to oral NSAIDs, or patient at high risk of gastric bleeding with oral NSAIDs*.
- Pain relief of osteoarthritis involving the elbow, wrist, hand, knee, ankle and/or foot in a patient who cannot swallow solid oral dosage forms and is not currently taking any solid oral dosage form.

Diclofenac gel (Voltaren gel) is not covered for the following conditions:

- Use on the spine, hip, or shoulder.
- Used concurrently with an oral NSAID (includes COX-2 inhibitors) prescribed for the same condition.

*Patients at high risk of gastric bleeding include:

Age 60 years or greater; history of peptic ulcer disease or ulcer/GI bleeding related to NSAIDs; current regimen includes anticoagulant, prescription antiplatelet drug, corticosteroid or DMARD (disease-modifying and anti-rheumatic drug) therapy; or hereditary or acquired coagulation defect (e.g., hemophilia, Von Willebrand's disease, protein C or S deficiency, thrombocytopenia or chronic renal failure).

BOXED WARNING: CARDIOVASCULAR AND GASTROINTESTINAL RISK

Cardiovascular Risk

- Non-steroidal anti-inflammatory drugs (NSAIDs) may cause an increased risk of serious cardiovascular thrombotic events, myocardial infarction, and stroke, which can be fatal.
- Voltaren Gel is contraindicated for the treatment of peri-operative pain in the setting of coronary artery bypass graft (CABG) surgery.

Gastrointestinal Risk

- Non-steroidal anti-inflammatory drugs (NSAIDs), including Voltaren Gel, cause an increased risk of serious gastrointestinal adverse events including bleeding, ulceration, and perforation of

the stomach or intestines, which can be fatal. Elderly patients are at greater risk for serious gastrointestinal events.

DOSAGE:

Adults: Apply 2 g for each elbow, wrist, or hand, and 4 g for each knee, ankle, or foot four times daily. Do not apply more than 16 g daily to any single joint of the lower extremities, or more than 8 g daily to any single joint of the upper extremities. Total dose should not exceed 32 g per day, over all affected joints.

REFERENCES:

Drug Facts and Comparisons eAnswers. Wolters Kluwer. Accessed March 2011.

Voltaren Gel. DRUGDEX Evaluations. Micromedex 2.0. Thomson Reuters. March 2011.

Voltaren Gel ® (diclofenac gel 1%) prescribing information. Endo Pharmaceuticals. Chadds Ford, PA. March 2011.