TRIFLUENT PHARMA®



Diclofenac Potassium Tablets for NSAID Treatment

- Copay card available for eligible patients
- 25 mg tablets for customizable treatment plans
- Recommended to be taken at lowest effective dose

Diclofenac Potassium Tablets

25 mg 30 ct. & 60 ct.

30 ct. NDC: 73352-086-30

60 ct. NDC: 73352-086-60

INDICATIONS:

Diclofenac potassium tablets are indicated:

- For treatment of primary dysmenorrhea
- For relief of mild to moderate pain
- For relief of the signs and symptoms of osteoarthritis
- For relief of the signs and symptoms of rheumatoid arthritis

ADVERSE REACTIONS:

The following adverse reactions are discussed in greater detail in other sections of the labeling:

- Cardiovascular Thrombotic Events
- GI Bleeding, Ulceration, and Perforation
- Hepatotoxicity
- Hypertension
- Heart Failure and Edema
- Renal Toxicity and Hyperkalemia
- Anaphylactic Reactions
- Serious Skin Reactions
- Hematologic Toxicity

HYPERTENSION:

NSAIDs, including diclofenac potassium tablets, can lead to new onset of hypertension or worsening of preexisting hypertension, either of which may contribute to the increased incidence of CV events. Patients taking angiotensin converting enzyme (ACE) inhibitors, thiazide diuretics or loop diuretics may have impaired response to these therapies when taking NSAIDs. Monitor blood pressure (BP) during the initiation of NSAID treatment and throughout the course of therapy.

HEART FAILURE AND EDEMA:

The Coxib and traditional NSAID Trialists' Collaboration meta-analysis of randomized controlled trials demonstrated an approximately two-fold increase in hospitalization for heart failure in COX-2 selective-treated patients and nonselective NSAID-treated patients compared to placebo-treated patients. In a Danish National Registry study of patients with heart failure, NSAID use increased the risk of MI, hospitalization for heart failure, and death. Additionally, fluid retention and edema have been observed in some patients treated with NSAIDs. Use of diclofenac may blunt the CV effects of several therapeutic agents used to treat these medical conditions (e.g., diuretics, ACE inhibitors, or angiotensin receptor blockers [ARBs]). Avoid the use of diclofenac potassium tablets in patients with severe heart failure unless the benefits are expected to outweigh the risk of worsening heart failure. If diclofenac potassium tablets are used in patients with severe heart failure, monitor patients for signs of worsening heart failure.

RENAL TOXICITY AND HYPERKALEMIA:

Renal Toxicity

Long-term administration of NSAIDs has resulted in renal papillary necrosis and other renal injury. Renal toxicity has also been seen in patients in whom renal prostaglandins have a compensatory role in the maintenance of renal perfusion. In these patients, administration of an NSAID may cause a dose-dependent reduction in prostaglandin formation and, secondarily, in renal blood flow, which may precipitate overt renal decompensation. Patients at greatest risk of this reaction are those with impaired renal function, dehydration, hypovolemia, heart failure, liver dysfunction,

For full Prescribing Information, see attached Product Insert.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit fda.gov/medwatch or call 1-800-FDA-1088.

those taking diuretics and ACE inhibitors or ARBs, and the elderly. Discontinuation of NSAID therapy is usually followed by recovery to the pretreatment state. No information is available from controlled clinical studies regarding the use of diclofenac potassium tablets in patients with advanced renal disease. The renal effects of diclofenac potassium tablets may hasten the progression of renal dysfunction in patients with preexisting renal disease. Correct volume status in dehydrated or hypovolemic patients prior to initiating diclofenac potassium tablets. Monitor renal function in patients with renal or hepatic impairment, heart failure, dehydration, or hypovolemia during use of diclofenac potassium tablets. Avoid the use of diclofenac potassium tablets in patients with advanced renal disease unless the benefits are expected to outweigh the risk of worsening renal function. If diclofenac potassium tablets are used in patients with advanced renal disease, monitor patients for signs of worsening renal function.

Hyperkalemia
Increases in serum potassium concentration, including hyperkalemia, have been reported with use of NSAIDs, even in some patients without renal impairment. In patients with normal renal function, these effects have been attributed to a hyporeninemic-hypoaldosteronism state.

ANAPHYLACTIC REACTIONS:
Diclofenac has been associated with anaphylactic reactions in patients with and without known hypersensitivity to diclofenac and in patients with aspirin-sensitive asthma.

EXACERBATION OF ASTHMA RELATED TO ASPIRIN SENSITIVITY:
A subpopulation of patients with asthma may have aspirin-sensitive asthma which may include chronic rhinosinusitis complicated by nasal polyps; severe, potentially fatal bronchospasm; and/or intolerance to aspirin and other NSAIDs. Because cross-reactivity between aspirin and other NSAIDs has been reported in such aspirin-sensitive patients, diclofenac potassium tablets are contraindicated in patients with this form of aspirin sensitivity. When diclofenac potassium tablets are used in patients with preexisting asthma (without known aspirin sensitivity), monitor patients for changes in the signs and symptoms of asthma.

SERIOUS SKIN REACTIONS:
NSAIDs, including diclofenac, can cause serious skin adverse events such as exfoliative dermatitis, Stevens-Johnson Syndrome (SJS), and toxic epidermal necrolysis (TEN), which can be fatal. These serious events may occur without warning. Inform patients about the signs and symptoms of serious skin reactions and discontinue the use of diclofenac potassium tablets at the first appearance of skin rash or any other sign of hypersensitivity. Diclofenac potassium tablets are contraindicated in patients with previous serious skin reactions to NSAIDs.

COPAY INFORMATION

PATIENTS May Pay As Little As $0*

*Full terms and conditions at trifluentpharma.com/copay

HOW TO WRITE:

Diclofenac Potassium Tablets

Take 2 tablets by mouth 3-4 times daily as directed.

☐ 25 mg

Dispense as written

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TRIFLUENTPHARMA.COM

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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 treatment and may increase with duration of use (see WARNINGS).
- Diclofenac Potassium tablets are contraindicated in the setting of coronary artery bypass graft (CABG) surgery (see CONTRAINDICATIONS, WARNINGS).

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 (see WARNINGS).