Diclofenac Sodium Delayed-Release (diclofenac sodium) - Drug Summary

Sandoz Inc.

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Diclofenac Sodium Delayed-Release (diclofenac sodium)

BOXED WARNING

NSAIDs cause an increased risk of serious cardiovascular (CV) thrombotic events (eg, MI, stroke), which can be fatal; risk may occur early in treatment and may increase w/ duration of use. Contraindicated in the setting of CABG surgery. NSAIDs cause an increased risk of serious GI adverse events (eg, bleeding, ulceration, perforation of the stomach/intestines), which can be fatal and can occur at any time during use and w/o warning symptoms; elderly patients are at greater risk.

COMMON BRAND NAMES

Voltaren Delayed-Release Tablets (Discontinued), Diclofenac Sodium Delayed-Release

THERAPEUTIC CLASS

NSAID

DEA CLASS

RX

ADULT DOSAGE & INDICATIONS

Osteoarthritis

100-150mg/day in divided doses (50mg bid or tid, or 75mg bid)

Rheumatoid Arthritis

150-200mg/day in divided doses (50mg tid or qid, or 75mg bid)

Ankylosing Spondylitis

Acute or Long-Term Use:
100-125mg/day, administered as 25mg qid, w/ an extra 25mg dose hs if necessary

ADMINISTRATION

Oral route

HOW SUPPLIED

Tab, Delayed-Release: 25mg, 50mg, 75mg

CONTRAINDICATIONS

Known hypersensitivity to diclofenac; history of asthma, urticaria, or allergic-type reactions after taking aspirin (ASA) or other NSAIDs; treatment in the setting of CABG surgery.

WARNINGS/PRECAUTIONS

Use lowest effective dose for the shortest duration possible. Increased CV thrombotic risk reported at higher doses. Avoid in patients w/ a recent MI unless benefits outweigh the risks; if used, monitor for signs of cardiac ischemia. May cause HTN or worsen preexisting HTN. Fluid retention and edema reported. Avoid in patients w/ severe heart failure (HF) unless benefits outweigh the risks; if used, monitor for signs of worsening HF. Use w/ extreme caution in patients w/ history of ulcer disease or GI bleeding, or risk factors for GI bleeding (eg, longer

duration of NSAID therapy, older age, poor general health status). D/C if a serious GI adverse event is suspected, until event is ruled out; for high-risk patients, consider alternate therapies that do not involve NSAIDs. Renal papillary necrosis and other renal injury reported w/ long-term use. Renal toxicity also reported in patients in whom renal prostaglandins have a compensatory role in the maintenance of renal perfusion; increased risk w/ renal/hepatic impairment, HF, and in elderly. Caution in patients w/ considerable dehydration. Not recommended w/ advanced renal disease; if therapy must be initiated, closely monitor renal function. D/C if renal disease develops. May cause elevation of LFTs or severe hepatic reactions (eg, jaundice, fatal fulminant hepatitis, liver necrosis, liver failure); d/c if liver disease develops, systemic manifestations occur, or abnormal LFTs persist/worsen. Anaphylactic reactions may occur; avoid w/ ASA triad. May cause serious skin reactions (eg, exfoliative dermatitis, Stevens-Johnson syndrome, toxic epidermal necrolysis); d/c at 1st appearance of skin rash or any other sign of hypersensitivity. Avoid in late pregnancy; may cause premature closure of ductus arteriosus. Not a substitute for corticosteroids or for the treatment of corticosteroid insufficiency. May mask signs of inflammation and fever. Anemia may occur; monitor Hgb/Hct if anemia develops. May inhibit platelet aggregation and prolong bleeding time; carefully monitor patients w/ coagulation disorders. Caution w/ preexisting asthma. Caution in elderly.

ADVERSE REACTIONS

Abdominal pain, constipation, diarrhea, dyspepsia, flatulence, gross bleeding/perforation, heartburn, N/V, GI ulcers, abnormal renal function, anemia, dizziness, edema, elevated liver enzymes, headaches.

DRUG INTERACTIONS

May diminish the antihypertensive effect of ACE inhibitors. Increased risk of renal toxicity w/ diuretics and ACE inhibitors; monitor renal function. Not recommended w/ ASA due to potential for increased adverse effects. May reduce the natriuretic effect of thiazide and loop diuretics. May increase lithium levels; monitor for lithium toxicity. May enhance methotrexate toxicity; caution w/ concomitant use. May increase cyclosporine's nephrotoxicity; use caution w/ concomitant use. Synergistic effect on GI bleeding w/ warfarin. Monitor patients receiving anticoagulants. Increased risk of GI bleeding w/ oral corticosteroids, anticoagulants, smoking, and alcohol use. May blunt the CV effects of several therapeutic agents used to treat fluid retention and edema (eg, diuretics, ACE inhibitors, ARBs). Coadministration w/ CYP2C9 inhibitors (eg, voriconazole) may enhance exposure and toxicity, whereas coadministration w/ CYP2C9 inducers (eg, rifampin) may lead to compromised efficacy; use caution and adjust dosage if warranted. Caution w/ potentially hepatotoxic drugs (eg, antibiotics, antiepileptics).

PREGNANCY AND LACTATION

Pregnancy: Category C.
Lactation: Not for use in nursing.

MECHANISM OF ACTION

NSAID; mechanism not established. Suspected to inhibit prostaglandin synthetase and exhibits anti-inflammatory, analgesic, and antipyretic activities.

PHARMACOKINETICS

Absorption: Absolute bioavailability (55%); T_{max}=2.3 hrs. **Distribution:** V_d=1.4L/kg; plasma protein binding (>99%). **Metabolism:** Glucuronidation and sulfation. **Elimination:** Urine (65%, conjugates of unchanged diclofenac plus metabolites), bile (35%, conjugates of unchanged diclofenac plus metabolites); $T_{1/2}$=2.3 hrs.

ASSESSMENT

Assess for history of asthma, urticaria, or allergic-type reactions w/ ASA or other NSAIDs, ASA triad, recent MI, severe HF, history of ulcer disease or GI bleeding, coagulation disorders, renal/hepatic impairment, pregnancy/nursing status, any other conditions where treatment is contraindicated or cautioned, and possible drug interactions. Obtain baseline BP.

MONITORING

Monitor for GI bleeding/ulceration/perforation, CV thrombotic events, MI, stroke, HTN, fluid retention, edema, serious skin reactions, anaphylactic reactions, and other adverse reactions. Monitor BP, CBC, bleeding time, LFTs, renal function, and chemistry profile periodically.

PATIENT COUNSELING

Instruct to seek medical advice if symptoms of CV events, GI ulceration/bleeding, skin/hypersensitivity reactions, congestive HF, hepatotoxicity, or anaphylactic reactions occur. Advise to d/c therapy immediately and contact physician if any type of rash or signs/symptoms of hepatotoxicity occur. Inform that medication should be avoided in late pregnancy.

STORAGE

20-25°C (68-77°F). Protect from moisture.

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