Voltaren XR (diclofenac sodium) - Drug Summary

Novartis Pharmaceuticals Corporation

Related Drug Information

Voltaren-XR
(diclofenac sodium)

BOXED WARNING

NSAIDs may cause an increased risk of serious cardiovascular (CV) thrombotic events, myocardial infarction (MI), stroke, and serious GI adverse events including inflammation, bleeding, ulceration, and perforation of the stomach or intestines, which may be fatal. Contraindicated for the treatment of perioperative pain in the setting of coronary artery bypass graft (CABG) surgery.

THERAPEUTIC CLASS

NSAID

DEA CLASS

RX

ADULT DOSAGE & INDICATIONS

Osteoarthritis

100mg qd

Rheumatoid Arthritis

100mg qd-bid

ADMINISTRATION

Oral route

HOW SUPPLIED

Tab, Extended-Release: 100mg

CONTRAINDICATIONS

Aspirin (ASA) or other NSAID allergy that precipitates asthma, urticaria, or allergic-type reactions. Treatment of perioperative pain in the setting of CABG surgery.

WARNINGS/PRECAUTIONS

Use lowest effective dose for the shortest duration possible. Not a substitute for corticosteroids or to treat corticosteroid insufficiency. May lead to onset of new HTN or worsening of preexisting HTN; monitor BP closely. Fluid retention and edema reported; caution with fluid retention or heart failure (HF). Extreme caution with a prior history of ulcer disease, and/or GI bleeding. Caution when initiating treatment in patients with considerable dehydration. Renal papillary necrosis and other renal injury reported after long-term use. Not recommended for use with advanced renal disease; if therapy must be initiated, monitor renal function. Anaphylactoid reactions may occur; avoid in patients with ASA triad. May cause serious skin adverse events (eg, exfoliative dermatitis, Stevens-Johnson syndrome [SJS], toxic epidermal necrolysis). Avoid in late pregnancy; may cause premature closure of ductus arteriosus. May cause elevations of LFTs; d/c if liver disease develops or systemic manifestations occur. Caution in elderly and debilitated patients. Anemia may occur; with long-term use, monitor Hgb/Hct if signs or symptoms of anemia develop. May inhibit platelet aggregation and prolong bleeding time; monitor with coagulation disorders. Caution with asthma and avoid with ASA-sensitive asthma.

ADVERSE REACTIONS

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

DRUG INTERACTIONS

Increased adverse effects with ASA; avoid use. May enhance methotrexate toxicity and increase nephrotoxicity of cyclosporine; caution with coadministration. May diminish antihypertensive effect of ACE inhibitors. Patients taking thiazides and loop diuretics may have impaired response to these therapies. ACE inhibitors and diuretics may precipitate overt renal decompensation. May reduce natriuretic effect of furosemide and thiazides. May increase lithium levels; monitor for toxicity. Synergistic effects with warfarin on GI bleeding. May increase risk of GI bleeding with oral corticosteroids/anticoagulants, tobacco, or alcohol use. Caution with hepatotoxic drugs (eg, antibiotics, antiepileptics). Caution with CYP2C9 inhibitors or inducers (eg, voriconazole, rifampin); dosage adjustment may be warranted.

PREGNANCY AND LACTATION

Category C, not for use in nursing.

MECHANISM OF ACTION

NSAID; not known, suspected to inhibit prostaglandin synthetase.

PHARMACOKINETICS

Absorption: Absolute bioavailability (55%); T_{max}=5.3 hrs. **Distribution:** V_d=1.4L/kg; plasma protein binding (>99%). **Metabolism:** Liver (glucuronidation and sulfation). **Elimination:** Urine (65%), bile (35%); $T_{1/2}$=2.3 hrs.

ASSESSMENT

Assess for CV disease or risk factors, fluid retention, edema, conditions affected by platelet function alterations, GI events or risk factors, renal/hepatic function, any other conditions where treatment is contraindicated or cautioned, pregnancy/nursing status, and possible drug interactions. Assess baseline BP, CBC, and chemistry profile.

MONITORING

Monitor for signs/symptoms of GI events, CV thrombotic events, congestive HF, HTN, allergic or skin reactions, hematological effects (eg, anemia, prolongation of bleeding time), renal papillary necrosis or other renal injury/toxicity, hepatotoxicity. Monitor BP, CBC, and chemistry profile periodically.

PATIENT COUNSELING

Advise to seek medical attention if signs and symptoms of hepatotoxicity, anaphylactic/anaphylactoid reactions, skin reactions, CV events, GI ulceration or bleeding, weight gain, or edema occur. Inform of pregnancy risks and instruct to avoid use during late pregnancy.

STORAGE

Protect from moisture. Do not store above 30°C (86°F).

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