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Ponstel

(Mefenamic Acid) - Shionogi

BOXED WARNING

May increase risk of serious cardiovascular (CV) thrombotic events, myocardial infarction (MI), and stroke; increased risk with duration of use and with cardiovascular disease (CVD) or risk factors for CVD. Contraindicated for the treatment of perioperative pain in the setting of coronary artery bypass graft (CABG) surgery. Increased risk of serious GI adverse events (eg, bleeding, ulceration, perforation of the stomach/intestines) that can be fatal and may occur at any time during use and without warning symptoms; elderly patients are at greater risk.

THERAPEUTIC CLASS

NSAID

DEA CLASS

RX

INDICATIONS

Treatment of primary dysmenorrhea. Relief of mild to moderate pain in patients ≥14 yrs of age, when therapy will not exceed 1 week.

ADULT DOSAGE

Adults: Individualize dose. Acute Pain: Initial: 500mg followed by 250mg q6h PRN for ≤1 week. Primary Dysmenorrhea: Initial: 500mg followed by 250mg q6h, starting with the onset of bleeding and associated symptoms. May be initiated with start of menses and should not be necessary for >2-3 days.

PEDIATRIC DOSAGE

Pediatrics: ≥14 Yrs: Individualize dose. Acute Pain: Initial: 500mg followed by 250mg q6h PRN for ≤1 week. Primary Dysmenorrhea: Initial: 500mg followed by 250mg q6h, starting with the onset of bleeding and associated symptoms. May be initiated with start of menses and should not be necessary for >2-3 days.

HOW SUPPLIED

Cap: 250mg

CONTRAINDICATIONS

Preexisting renal disease, acute active ulceration or chronic inflammation of the upper/lower GI tract. History of asthma, urticaria, or allergic-type reactions after taking aspirin (ASA) or other NSAIDs. Treatment of perioperative pain in the setting of CABG surgery.

WARNINGS/PRECAUTIONS

Use lowest effective dose for shortest duration possible to minimize risk for CV events and adverse GI events. May lead to onset of new HTN or worsening of preexisting HTN; caution with HTN and monitor BP closely at initiation and throughout the course of therapy. Fluid retention and edema reported; caution with fluid retention or heart failure (HF). Caution with prior history of ulcer disease or GI bleeding. Increased risk of GI bleeding with longer duration of NSAID therapy, older age, and poor general health status; monitor for GI ulceration/bleeding and d/c therapy until a serious GI adverse event is ruled out. Consider alternate therapies that do not involve NSAIDs in high risk patients. Renal papillary necrosis, and other renal injury reported after long-term use. Increased risk of renal toxicity with impaired renal function, HF, and liver dysfunction. Not recommended for use with advanced renal disease. Anaphylactoid reactions may occur; avoid in patients with ASA triad. May cause serious skin adverse events (eg, exfoliative dermatitis, Stevens-Johnson syndrome, toxic epidermal necrolysis); d/c at 1st appearance of skin rash/hypersensitivity. Avoid in late pregnancy; may cause premature closure of ductus arteriosus. Not a substitute for corticosteroids nor treatment for corticosteroid insufficiency; abrupt discontinuation of corticosteroids may lead to disease exacerbation. Elevations of LFTs and severe hepatic reactions (eg, jaundice, fatal fulminant hepatitis, liver necrosis, hepatic failure) reported; d/c if liver/renal disease or systemic manifestations occur and if abnormal LFTs persist/worsen. Anemia reported; with long-term use, monitor Hgb/Hct if signs/symptoms of anemia develop. May inhibit platelet aggregation and prolong bleeding time; monitor patients with coagulation disorders. Caution with asthma and avoid with ASA-sensitive asthma. May alter lab test results. Caution in debilitated patients and elderly.

ADVERSE REACTIONS

Abdominal pain, constipation, diarrhea, dyspepsia, flatulence, gross bleeding/perforation, heartburn, GI ulcers, N/V, anemia, dizziness, edema, headache, rashes.

DRUG INTERACTIONS

Increased risk of GI bleeding with oral corticosteroids, anti-coagulants, alcohol use, and smoking. May have impaired response to thiazides or loop diuretics. Caution with CYP2C9 inhibitors. May diminish antihypertensive effects of ACE-inhibitors. ASA may increase adverse effects; concomitant use not recommeded. May reduce natriuretic effect of furosemide and thiazides; monitor for renal failure and diuretic efficacy. May increase lithium levels; monitor for lithium toxicity. Enhances methotrexate toxicity; caution with concomitant use. Warfarin may increase risk of GI bleeding.

Antacids containing magnesium hydroxide may increase mefenamic acid levels. May prolong PT with oral anticoagulants; monitor PT frequently.

PREGNANCY
Category C, not for use in nursing.

MECHANISM OF ACTION
NSAID (fenamate group); has not been established. May be related to prostaglandin synthetase inhibition.

PHARMACOKINETICS
Absorption: Rapid; C_{max}=10-20mcg/mL (1 single 1g dose), T_{max}=2-4 hrs. **Distribution:** V_d=1.06L/kg; plasma protein binding (>90%); found in breast milk. **Metabolism**: Via CYP2C9; oxidation, glucuronidation. **Elimination:** Urine (52%), feces (≤20%); $T_{1/2}$=2 hrs.

ASSESSMENT
Assess for history of asthma, urticaria, allergic-type reactions with ASA or NSAIDS, ASA triad, known hypersensitivity to the drug, CVD and its risk factors, HTN, HF, fluid retention, history of/risk factors for GI bleeding, pregnancy/nursing status, possible drug interactions, and other conditions where treatment is cautioned/contraindicated. Assess hepatic/renal function. Obtain baseline LFTs, and CBC.

MONITORING
Monitor for hypersensitivity reactions, CV thrombotic events, MI, stroke, GI bleeding, serious skin reactions, asthma, and other adverse effects. Monitor BP, LFTs, renal function, CBC count, and chemistry profile. May prolong PT with oral anti-coagulants; monitor PT frequently.

PATIENT COUNSELING
Advise to be alert for signs/symptoms of chest pain, SOB, weakness, slurring of speech, ulceration and bleeding, skin rash and blisters, fever, or other signs of hypersensitivity (eg, itching); instruct to seek medical advice when observing any indicative sign/symptom. Instruct to d/c therapy and contact physician immediately if any type of rash develops. Instruct to promptly report signs/symptoms of unexplained weight gain or edema. Instruct to d/c therapy and seek immediate medical therapy if hepatotoxicity (eg, nausea, fatigue, lethargy, pruritus, jaundice) occurs. Instruct to seek immediate emergency help if signs of anaphylactoid reaction (difficulty breathing, swelling of the face/throat) occur. Advise to avoid in late pregnancy.

ADMINISTRATION/STORAGE
Administration: Oral route. **Storage:** 20-25°C (68-77°F); excursions permitted to 15-30°C (59-86°F).