

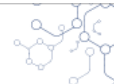
# PDR Search


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## Feldene (piroxicam) - Drug Summary

Pfizer Laboratories Div Pfizer Inc

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Feldene  
(piroxicam)

### BOXED WARNING

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

### THERAPEUTIC CLASS

NSAID

### DEA CLASS

RX

### ADULT DOSAGE & INDICATIONS

#### Rheumatoid Arthritis

**Usual:** 20mg qd; may divide daily dose

Adjust dose and frequency after observing response to initial therapy  
Use lowest effective dose for shortest duration consistent w/ individual patient treatment goals

#### Osteoarthritis

**Usual:** 20mg qd; may divide daily dose

Adjust dose and frequency after observing response to initial therapy  
Use lowest effective dose for shortest duration consistent w/ individual patient treatment goals

### DOSING CONSIDERATIONS

#### Elderly

Use caution; start at lower end of dosing range

#### Hepatic Impairment

May require reduced doses

### ADMINISTRATION

Oral route

### HOW SUPPLIED

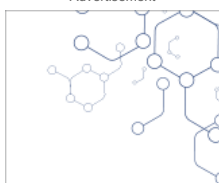
Cap: 10mg, 20mg

### CONTRAINDICATIONS

Patients who have experienced asthma, urticaria, or other allergic-type reactions after taking aspirin (ASA) or other NSAIDs. Treatment of perioperative pain in the setting of CABG surgery.

### WARNINGS/PRECAUTIONS

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May lead to onset of new HTN or worsening of preexisting HTN; caution w/ HTN. Fluid retention and edema reported; caution w/ fluid retention or heart failure (HF). Extreme caution 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); monitor for GI ulceration/bleeding, and d/c if serious GI adverse event occurs. Renal papillary necrosis and other renal injury reported w/ long-term use. Renal toxicity 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. Not recommended w/ advanced renal disease; if therapy must be initiated, closely monitor renal function. D/C if clinical signs and symptoms consistent w/ renal disease develop. Anaphylactoid reactions may occur; avoid w/ ASA-triad. May cause serious skin adverse events; d/c at 1st appearance of skin rash or any other sign of hypersensitivity. Combination of dermatological and/or allergic signs and symptoms suggestive of serum sickness occasionally reported. Avoid in late pregnancy; may cause premature closure of the ductus arteriosus. Not a substitute for corticosteroids or for the treatment of corticosteroid insufficiency. May mask signs of inflammation and fever. May cause elevation of LFTs or severe hepatic reactions; d/c if liver disease develops, systemic manifestations occur, or abnormal LFTs persist/worsen. Anemia may occur; monitor Hgb/Hct if signs/symptoms of anemia develop w/ long-term use. May inhibit platelet aggregation and prolong bleeding time; monitor patients w/ coagulation disorders. Perform ophthalmic evaluations if visual complaints develop. Caution w/ preexisting asthma and avoid w/ ASA-sensitive asthma. May delay or prevent rupture of ovarian follicles, which has been associated w/ reversible infertility in women; consider withdrawal of therapy in women who have difficulties conceiving or who are undergoing investigation of infertility. Caution in debilitated and poor CYP2C9 metabolizers.

## ADVERSE REACTIONS

CV thrombotic events, MI, stroke, GI bleeding, GI ulceration, stomach/intestinal perforation, dizziness, headache, pruritus, rash, tinnitus, anorexia, abdominal pain, diarrhea.

## DRUG INTERACTIONS

Monitor for a change in dosage requirements when administered w/ other highly protein bound drugs. Not recommended w/ ASA; potential for increased adverse effects. May enhance methotrexate toxicity; use caution when coadministered. May diminish the antihypertensive effect of ACE inhibitors. May reduce the natriuretic effect of thiazide and loop (eg, furosemide) diuretics. Increased risk of renal toxicity w/ diuretics and ACE inhibitors; monitor renal function. May elevate lithium levels; monitor for signs of lithium toxicity. Increased risk of GI bleeding w/ oral corticosteroids or anticoagulants (eg, warfarin), smoking, and alcohol. Monitor patients receiving anticoagulants.

## PREGNANCY AND LACTATION

Category C (1st and 2nd trimester) and D (3rd trimester), caution in nursing.

## MECHANISM OF ACTION

NSAID; not established. May be related to prostaglandin synthetase inhibition.

## PHARMACOKINETICS

**Absorption:** Well absorbed.  $C_{max}$ =1.5-2mcg/mL (single dose), 3-8mcg/mL (multiple doses);  $T_{max}$ =3-5 hrs. **Distribution:**  $V_d$ =0.14L/kg; plasma protein binding (99%); found in breast milk. **Metabolism:** Hydroxylation via CYP2C9, conjugation, cyclodehydration, hydrolysis, decarboxylation, ring contraction, and N-demethylation; 5'-hydroxy-piroxicam (major metabolite). **Elimination:** Urine and feces (5% unchanged);  $T_{1/2}$ =50 hrs.

## ASSESSMENT

Assess for history of asthma, urticaria, or allergic-type reactions w/ ASA or other NSAIDs, ASA-triad, CVD, risk factors for CVD, history of ulcer disease or GI bleeding, risk factors for GI bleeding, coagulation disorders, any other conditions where treatment is contraindicated or cautioned, renal/hepatic function, pregnancy/nursing status, and possible drug interactions.

## MONITORING

Monitor for CV events, GI events, anaphylactoid/skin/hypersensitivity reactions, hematological effects, ophthalmologic effects, delayed ovulation, and other adverse reactions. Monitor BP, LFTs, renal function, CBC, and chemistry profiles.

## PATIENT COUNSELING

Inform to seek medical advice if signs and symptoms of CV events, GI ulceration/bleeding, skin/hypersensitivity reactions, unexplained weight gain or edema, hepatotoxicity, and anaphylactoid reactions occur. Advise to d/c the drug immediately if any type of rash, or if signs/symptoms of hepatotoxicity occur. Inform that medication should be avoided in late pregnancy. Advise females of reproductive potential who desire pregnancy that therapy may be associated w/ a reversible delay in ovulation; inform that use of therapy is not recommended for women who have difficulties conceiving, or who are undergoing investigation of infertility.

## STORAGE

<30°C (86°F).

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