Anaprox/EC-Naprosyn/Naprosyn (naproxen); (naproxen sodium) - Drug Summary

Genentech, Inc.

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Naprosyn
(naproxen)

BOXED WARNING

NSAIDs may increase risk of serious cardiovascular thrombotic events, MI, and stroke; increased risk with duration of use and with cardiovascular disease (CVD) or risk factors for CVD. Increased risk of serious GI adverse events (eg, bleeding, ulceration, and stomach/intestinal perforation) that can be fatal and occur anytime during use without warning symptoms; elderly patients are at a greater risk. Contraindicated for treatment of perioperative pain in the setting of CABG surgery.

COMMON BRAND NAMES

EC-Naprosyn, Anaprox, Anaprox DS

THERAPEUTIC CLASS

NSAID

DEA CLASS

RX

ADULT DOSAGE & INDICATIONS

Gout

Acute Attack:

Naprosyn:
Initial: 750mg, then 250mg q8h until attack subsides

Anaprox:
Initial: 825mg, then 275mg q8h until attack subsides

Bursitis

Anaprox/Anaprox DS:
Initial: 550mg, then 550mg q12h or 275mg q6-8h as required
Max: 1375mg/day initially, 1100mg/day thereafter

Rheumatoid Arthritis

Naprosyn:
250mg, 375mg, or 500mg bid

EC-Naprosyn:
375mg or 500mg bid

Anaprox:
275mg bid

Anaprox DS:
550mg bid

Titrate: Adjust dose/frequency up or down depending on clinical response; may increase to 1500mg/day for ≤6 months if patient can tolerate lower doses well

Ankylosing Spondylitis

Naprosyn:
250mg, 375mg, or 500mg bid

EC-Naprosyn:
375mg or 500mg bid

Anaprox:
275mg bid

Anaprox DS:
550mg bid

Titrate: Adjust dose/frequency up or down depending on clinical response; may increase to 1500mg/day for ≤6 months if patient can tolerate lower doses well

Pain

Anaprox/Anaprox DS:
Initial: 550mg, then 550mg q12h or 275mg q6-8h as required
Max: 1375mg/day initially, 1100mg/day thereafter

Primary Dysmenorrhea

Anaprox/Anaprox DS:
Initial: 550mg, then 550mg q12h or 275mg q6-8h as required
Max: 1375mg/day initially, 1100mg/day thereafter

Osteoarthritis

Naprosyn:
250mg, 375mg, or 500mg bid

EC-Naprosyn:
375mg or 500mg bid

Anaprox:
275mg bid

Anaprox DS:
550mg bid

Titrate: Adjust dose/frequency up or down depending on clinical response; may increase to 1500mg/day for ≤6 months if patient can tolerate lower doses well

PEDIATRIC DOSAGE & INDICATIONS

Juvenile Arthritis

≥2 Years:
Sus:
Usual: 5mg/kg bid

DOSING CONSIDERATIONS

Renal Impairment
Start w/ lower end of dosing range
Moderate to Severe (CrCl <30mL/min): Not recommended

Hepatic Impairment
Start w/ lower end of dosing range

Elderly
Start w/ lower end of dosing range

ADMINISTRATION

Oral route

EC-Naprosyn
Do not chew, crush, or break

HOW SUPPLIED

Sus: (Naprosyn) 125mg/5mL [473mL]; Tab: (Naprosyn) 250mg*, 375mg, 500mg*, (Anaprox [naproxen sodium]) 275mg, (Anaprox DS [naproxen sodium]) 550mg*; Tab, Delayed-Release: (EC-Naprosyn) 375mg, 500mg
*scored

CONTRAINDICATIONS

History of asthma, urticaria, or other allergic-type reactions with ASA or other NSAIDs. Treatment of perioperative pain in the setting of CABG surgery.

WARNINGS/PRECAUTIONS

Use lowest effective dose for the shortest duration possible. May cause HTN or worsen preexisting HTN; monitor BP closely. Fluid retention and edema reported; caution with fluid retention, HTN, or HF. Caution with prior history of ulcer disease, GI bleeding, and risk factors for GI bleeding; monitor for GI ulceration/bleeding and d/c if serious GI event occurs. May exacerbate inflammatory bowel disease. Renal injury reported with long-term use; increased risk with renal/hepatic impairment, hypovolemia, HF, salt depletion, and in elderly. Not recommended with advanced renal disease or moderate to severe renal impairment (CrCl <30mL/min); monitor renal function closely and hydrate adequately. D/C if signs and symptoms consistent with renal disease develop. Anaphylactoid reactions may occur. Caution with asthma and avoid with ASA-sensitive asthma and the 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 or for the treatment of corticosteroid insufficiency. May mask signs of inflammation and fever. Periodically monitor Hgb if initial Hgb ≤10g and receiving long-term therapy. Perform ophthalmic studies if visual changes/disturbances occur. May cause elevations of LFTs or severe hepatic reactions; d/c if liver disease or systemic manifestations occur, or if abnormal LFTs persist/worsen. Caution with chronic alcoholic liver disease and other diseases with decreased/abnormal plasma proteins if high doses are administered; dosage adjustment may be required. Anemia reported; monitor Hgb/Hct if anemia develops. May inhibit platelet aggregation and prolong bleeding time; monitor patients with coagulation disorders. Monitor CBC and chemistry profile periodically with long-term treatment. (Sus, Anaprox/Anaprox DS) Contains Na^+; caution with severely restricted Na^+ intake. (EC-Naprosyn) Not recommended for initial treatment of acute pain.

ADVERSE REACTIONS

Cardiovascular (CV) thrombotic events, MI, stroke, GI adverse events, edema, drowsiness, dizziness, constipation, heartburn, abdominal pain, nausea, headache, tinnitus, dyspnea, pruritus.

DRUG INTERACTIONS

Avoid with other naproxen products. Not recommended with ASA. Risk of renal toxicity with diuretics, ACE inhibitors, and ARBs. May reduce natriuretic effect of loop (eg, furosemide) or thiazide diuretics; monitor for signs of renal failure and diuretic efficacy. May diminish antihypertensive effect of ACE inhibitors, ARBs, or β-blockers (eg, propranolol); monitor changes in BP. May result in deterioration of renal function, including possible acute renal failure with ACE inhibitors or ARBs; monitor closely for signs of worsening renal function. May enhance methotrexate toxicity; caution with concomitant use. May increase lithium levels and reduce renal lithium clearance; monitor for lithium toxicity. Increased risk of GI bleeding with SSRIs, oral corticosteroids, anticoagulants, alcohol, and smoking; monitor carefully. Synergistic effect on GI bleeding with warfarin. Potential for interaction with other albumin-bound drugs (eg, coumarin-type anticoagulants, sulfonylureas, hydantoins, other NSAIDs, ASA); dose adjustment with hydantoin, sulfonamide, or sulfonylurea may be required. Probenecid significantly increases plasma levels and extends $T_{1/2}$. Antacids, sucralfate, and cholestyramine can delay absorption. (EC-Naprosyn) Not recommended with H_2-blockers, sucralfate, or intensive antacid therapy.

PREGNANCY AND LACTATION

Category C, not for use in nursing.

MECHANISM OF ACTION

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

PHARMACOKINETICS

Absorption: Rapid and complete. Bioavailability (95%). Naprosyn: C_{max}=97.4mcg/mL, AUC=767mcg•hr/mL, T_{max}=2-4 hrs (tab), 1-4 hrs (sus). EC-Naprosyn: C_{max}=94.9mcg/mL, AUC=845mcg•hr/mL, T_{max}=4 hrs. Anaprox (naproxen sodium): T_{max}=1-2 hrs. **Distribution:** V_d=0.16L/kg; plasma protein binding (>99%); found in breast milk. **Metabolism:** Liver (extensive); 6-0-desmethyl naproxen (metabolite). **Elimination:** Urine (95%; <1% unchanged, <1% 6-0-desmethyl naproxen, 66-92% conjugates), feces (≤3%); $T_{1/2}$=12-17 hrs.

ASSESSMENT

Assess for history of asthma, urticaria, or allergic-type reactions with ASA or other NSAIDs, ASA triad, CVD, risk factors for CVD, HTN, fluid retention, HF, salt restriction, history of ulcer disease, history of/risk factors for GI bleeding, general health status, history of IBD, renal/hepatic impairment, hypovolemia, decreased/abnormal plasma proteins, coagulation disorders, pregnancy/nursing status, and for possible drug interactions. Obtain baseline CBC and BP.

MONITORING

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

PATIENT COUNSELING

Inform to seek medical advice if symptoms of CV events, GI ulceration/bleeding, skin/hypersensitivity reactions, unexplained weight gain or edema, hepatotoxicity, or anaphylactoid reactions occur. Instruct to avoid use in late pregnancy. Instruct to use caution when performing activities that require alertness if drowsiness, dizziness, vertigo, or depression occurs.

STORAGE

15-30°C (59-86°F). (Sus) Avoid excessive heat, >40°C (104°F). Shake gently before use.

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