Naproxen

Drug Information Provided by Lexi-Comp

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ALERT: U.S. Boxed Warning

The FDA-approved labeling includes a boxed warning. See Warnings/Precautions section for a concise summary of this information. For verbatim wording of the boxed warning, consult the product labeling or www.fda.gov.

Medication Safety Issues

Sound-alike/look-alike issues:

Naproxen may be confused with Natacyn®, Nebcin®

Aleve® may be confused with Alesse®

Anaprox® may be confused with Anaspaz®, Avapro®

Naprelan® may be confused with Naprosyn®

Naprosyn® may be confused with Naprelan®, Natacyn®, Nebcin®

International issues:

Flogen® [Mexico] may be confused with Flovent® which is a brand name for fluticasone in the U.S.

Flogen® [Mexico] may be confused with Floxin® which is a brand name for ofloxacin in the U.S.

Pronunciation

(na PROKS en)

U.S. Brand Names

- Aleve® [OTC]
- Anaprox®
- Anaprox® DS
- EC-Naprosyn®
- Mediproxen [OTC]
- Midol® Extended Relief [OTC]
- Naprelan®

- Naprosyn®
- Pamprin® Maximum Strength All Day Relief [OTC]

Index Terms

- Naproxen Sodium

Generic Available

Yes

Canadian Brand Names

- Anaprox®
- Anaprox® DS
- Apo-Napro-Na DS®
- Apo-Napro-Na®
- Apo-Naproxen EC®
- Apo-Naproxen SR®
- Apo-Naproxen®
- Gen-Naproxen EC
- Mylan-Naproxen EC
- Naprosyn®
- Naxen®
- Naxen® EC
- Novo-Naproc EC
- Novo-Naprox
- Novo-Naprox Sodium
- Novo-Naprox Sodium DS
- Novo-Naprox SR
- Nu-Naprox
- PMS-Naproxen EC
- PRO-Naproxen EC
- Riva-Naproxen
- Sab-Naproxen

Pharmacologic Category

- Nonsteroidal Anti-inflammatory Drug (NSAID), Oral

Use: Labeled Indications

Management of ankylosing spondylitis, osteoarthritis, and rheumatoid disorders (including juvenile rheumatoid arthritis); acute gout; mild-to-moderate pain; tendonitis, bursitis; dysmenorrhea; fever

Use: Dental

Management of pain and swelling

Pregnancy Risk Factor

C

Pregnancy Considerations

Adverse events were not observed in the initial animal reproduction studies; therefore, the manufacturer classifies naproxen as pregnancy category C. Naproxen crosses the placenta and can be detected in fetal tissue and the serum of newborn infants following in utero exposure. NSAID exposure during the first trimester is not strongly associated with congenital malformations; however, cardiovascular anomalies and cleft palate have been observed following NSAID exposure in some studies. The use of a NSAID close to conception may be

associated with an increased risk of miscarriage. Nonteratogenic effects have been observed following NSAID administration during the third trimester including: Myocardial degenerative changes, prenatal constriction of the ductus arteriosus, fetal tricuspid regurgitation, failure of the ductus arteriosus to close postnatally; renal dysfunction or failure, oligohydramnios; gastrointestinal bleeding or perforation, increased risk of necrotizing enterocolitis; intracranial bleeding (including intraventricular hemorrhage), platelet dysfunction with resultant bleeding; pulmonary hypertension. Because they may cause premature closure of the ductus arteriosus, use of NSAIDs late in pregnancy should be avoided (use after 31 or 32 weeks gestation is not recommended by some clinicians). The chronic use of NSAIDs in women of reproductive age may be associated with infertility that is reversible upon discontinuation of the medication. A registry is available for pregnant women exposed to autoimmune medications including naproxen. For additional information contact the Organization of Teratology Information Specialists, OTIS Autoimmune Diseases Study, at (877) 311-8972.

Lactation

Enters breast milk/not recommended (AAP rates "compatible")

Breast-Feeding Considerations

Small amounts of naproxen are excreted into breast milk. Naproxen has been detected in the urine of a breast-feeding infant. Breast-feeding is not recommended by the manufacturer. The AAP considers naproxen to be "usually compatible with breast-feeding." In a study which included 20 mother-infant pairs, there were two cases of drowsiness and one case of vomiting in the breast-fed infants. Maternal naproxen dose, duration, and relationship to breast-feeding were not provided.

Contraindications

Hypersensitivity to naproxen, aspirin, other NSAIDs, or any component of the formulation; perioperative pain in the setting of coronary artery bypass graft (CABG) surgery

Warnings/Precautions

Boxed warnings:

• Cardiovascular events: See “Concerns related to adverse effects” below.

• Coronary artery bypass graft surgery: See “Disease-related concerns” below.

• Gastrointestinal events: See “Concerns related to adverse effects” below.

Concerns related to adverse effects:

• Anaphylactoid reactions: Even in patients without prior exposure anaphylactoid reactions may occur; patients with "aspirin triad" (bronchial asthma, aspirin intolerance, rhinitis) may be at increased risk. Do not use in patients who experience bronchospasm, asthma, rhinitis, or urticaria with NSAID or aspirin therapy.

• Cardiovascular events: **[U.S. Boxed Warning]: NSAIDs are associated with an increased risk of adverse cardiovascular thrombotic events, including MI and stroke.** Risk may be increased with duration of use or pre-existing cardiovascular risk factors or disease. Carefully evaluate individual cardiovascular risk profiles prior to prescribing. Use caution with fluid retention. Avoid use in heart failure. Concurrent administration of ibuprofen, and potentially other nonselective NSAIDs, may interfere with aspirin's cardioprotective effect. Use the lowest effective dose for the shortest duration of time, consistent with individual patient goals, to reduce risk of cardiovascular events; alternate therapies should be considered for patients at high risk.

• CNS effects: May cause drowsiness, dizziness, blurred vision, and other neurologic effects which may impair physical or mental abilities; patients must be cautioned about performing tasks which require mental alertness (eg, operating machinery or driving). Discontinue use

with blurred or diminished vision and perform ophthalmologic exam. Periodically evaluate vision in all patients receiving long term therapy.

• Gastrointestinal events: **[U.S. Boxed Warning]: NSAIDs may increase risk of gastrointestinal irritation, inflammation, ulceration, bleeding, and perforation.** These events may occur at any time during therapy and without warning. Use caution with a history of GI disease (bleeding or ulcers), concurrent therapy with aspirin, anticoagulants and/or corticosteroids, smoking, use of alcohol, the elderly or debilitated patients. Use the lowest effective dose for the shortest duration of time, consistent with individual patient goals, to reduce risk of GI adverse events; alternate therapies should be considered for patients at high risk. When used concomitantly with ?325 mg of aspirin, a substantial increase in the risk of gastrointestinal complications (eg, ulcer) occurs; concomitant gastroprotective therapy (eg, proton pump inhibitors) is recommended (Bhatt, 2008).

• Hematologic effects: Platelet adhesion and aggregation may be decreased; may prolong bleeding time; patients with coagulation disorders or who are receiving anticoagulants should be monitored closely. Anemia may occur; patients on long-term NSAID therapy should be monitored for anemia. Rarely, NSAID use has been associated with potentially severe blood dyscrasias (eg, agranulocytosis, thrombocytopenia, aplastic anemia).

• Hyperkalemia: NSAID use may increase the risk of hyperkalemia, particularly in the elderly, diabetics, renal disease, and with concomitant use of other agents capable of inducing hyperkalemia (eg, ACE-inhibitors). Monitor potassium closely.

• Skin reactions: NSAIDs may cause serious skin adverse events including exfoliative dermatitis, Stevens-Johnson syndrome (SJS), and toxic epidermal necrolysis (TEN); discontinue use at first sign of skin rash or hypersensitivity.

Disease-related concerns:

• Aseptic meningitis: May increase the risk of aseptic meningitis, especially in patients with systemic lupus erythematosus (SLE) and mixed connective tissue disorders.

• Asthma: Do not administer to patients with aspirin-sensitive asthma; severe bronchospasm may occur. Use caution in patients with other forms of asthma.

• Coronary artery bypass graft surgery: **[U.S. Boxed Warning]: Use is contraindicated for treatment of perioperative pain in the setting of coronary artery bypass graft (CABG) surgery.** Risk of MI and stroke may be increased with use following CABG surgery.

• Hepatic impairment: Use with caution in patients with decreased hepatic function. Closely monitor patients with any abnormal LFT. Severe hepatic reactions (eg, fulminant hepatitis, liver failure) have occurred with NSAID use, rarely; discontinue if signs or symptoms of liver disease develop, or if systemic manifestations occur.

• Hypertension: Use with caution; may cause new-onset hypertension or worsening of existing hypertension.

• Renal impairment: NSAID use may compromise existing renal function; dose-dependent decreases in prostaglandin synthesis may result from NSAID use, reducing renal blood flow which may cause renal decompensation. Patients with impaired renal function, dehydration, heart failure, liver dysfunction, those taking diuretics, and ACE inhibitors, and the elderly are at greater risk of renal toxicity. Rehydrate patient before starting therapy; monitor renal function closely. Not recommended for use in patients with advanced renal disease. Long-term NSAID use may result in renal papillary necrosis.

Special populations:

• Elderly: The elderly are at increased risk for adverse effects (especially peptic ulceration,

CNS effects, renal toxicity) from NSAIDs even at low doses.

• Pediatrics: Safety and efficacy have not been established in children <2 years of age. Not for self-medication (OTC use) in children <12 years of age.

Other warnings/precautions:

• Self-medication (OTC use): Prior to self-medication, patients should contact healthcare provider if they have had recurring stomach pain or upset, ulcers, bleeding problems, asthma, high blood pressure, heart or kidney disease, other serious medical problems, are currently taking a diuretic, anticoagulant, other NSAIDs, or are ?60 years of age. Recommended dosages and duration should not be exceeded, due to an increased risk of GI bleeding, MI, and stroke. Patients should stop use and consult a healthcare provider if symptoms get worse, newly appear, or continue; if an allergic reaction occurs; if feeling faint, vomit blood or have bloody/black stools; if having difficulty swallowing or heartburn, or if fever lasts for >3 days or pain >10 days. Consuming ?3 alcoholic beverages/day or taking longer than recommended may increase the risk of GI bleeding.

• Surgical/dental procedures: Withhold for at least 4-6 half-lives prior to surgical or dental procedures.

Adverse Reactions

1% to 10%:

Cardiovascular: Edema (3% to 9%), palpitation (<3%)

Central nervous system: Dizziness (3% to 9%), drowsiness (3% to 9%), headache (3% to 9%), lightheadedness (<3%), vertigo (<3%)

Dermatologic: Pruritus (3% to 9%), skin eruption (3% to 9%), ecchymosis (3% to 9%), purpura (<3%), rash

Endocrine & metabolic: Fluid retention (3% to 9%)

Gastrointestinal: Abdominal pain (3% to 9%), constipation (3% to 9%), nausea (3% to 9%), heartburn (3% to 9%), diarrhea (<3%), dyspepsia (<3%), stomatitis (<3%), flatulence, gross bleeding/perforation, indigestion, ulcers, vomiting

Genitourinary: Abnormal renal function

Hematologic: Hemolysis (3% to 9%), ecchymosis (3% to 9%), anemia, bleeding time increased

Hepatic: LFTs increased

Ocular: Visual disturbances (<3%)

Otic: Tinnitus (3% to 9%), hearing disturbances (<3%)

Respiratory: Dyspnea (3% to 9%)

Miscellaneous: Diaphoresis (<3%), thirst (<3%)

<1%: Agranulocytosis, alopecia, anaphylactic/anaphylactoid reaction, angioneurotic edema, arrhythmia, aseptic meningitis, asthma, blurred vision, cognitive dysfunction, colitis, coma, confusion, CHF, conjunctivitis, cystitis, depression, dream abnormalities, dysuria, eosinophilia, eosinophilic pneumonitis, erythema multiforme, exfoliative dermatitis, glossitis, granulocytopenia, hallucinations, hematemesis, hepatitis, hyper-/hypoglycemia, hyper-/hypotension, infection, interstitial nephritis, melena, jaundice, leukopenia, liver failure, lymphadenopathy, menstrual disorders, malaise, MI, muscle weakness, myalgia, oliguria,

pancreatitis, pancytopenia, paresthesia, photosensitivity, pneumonia, polyuria, proteinuria, pyrexia, rectal bleeding, renal failure, renal papillary necrosis, respiratory depression, sepsis, Stevens-Johnson syndrome, tachycardia, seizure, syncope, thrombocytopenia, toxic epidermal necrolysis ulcerative stomatitis, vasculitis

Metabolism/Transport Effects

Substrate (minor) of CYP1A2, 2C9

Drug Interactions

ACE Inhibitors: Nonsteroidal Anti-Inflammatory Agents may diminish the antihypertensive effect of ACE Inhibitors. *Risk C: Monitor therapy*

Aminoglycosides: Nonsteroidal Anti-Inflammatory Agents may decrease the excretion of Aminoglycosides. Data only in premature infants. *Risk C: Monitor therapy*

Angiotensin II Receptor Blockers: Nonsteroidal Anti-Inflammatory Agents may diminish the therapeutic effect of Angiotensin II Receptor Blockers. The combination of these two agents may also significantly decrease glomerular filtration and renal function. *Risk C: Monitor therapy*

Anticoagulants: Antiplatelet Agents may enhance the anticoagulant effect of Anticoagulants. *Risk C: Monitor therapy*

Anticoagulants: Nonsteroidal Anti-Inflammatory Agents may enhance the anticoagulant effect of Anticoagulants. *Risk C: Monitor therapy*

Antidepressants (Tricyclic, Tertiary Amine): May enhance the antiplatelet effect of NSAID (Nonselective). *Risk C: Monitor therapy*

Antiplatelet Agents: May enhance the anticoagulant effect of other Antiplatelet Agents. *Risk C: Monitor therapy*

Antiplatelet Agents: Nonsteroidal Anti-Inflammatory Agents may enhance the adverse/toxic effect of Antiplatelet Agents. An increased risk of bleeding may occur. Nonsteroidal Anti-Inflammatory Agents may diminish the cardioprotective effect of Antiplatelet Agents. This interaction is likely specific to aspirin, and not to other antiplatelet agents. *Risk C: Monitor therapy*

Beta-Blockers: Nonsteroidal Anti-Inflammatory Agents may diminish the antihypertensive effect of Beta-Blockers. **Exceptions:** Levobunolol; Metipranolol. *Risk C: Monitor therapy*

Bile Acid Sequestrants: May decrease the absorption of Nonsteroidal Anti-Inflammatory Agents. *Risk D: Consider therapy modification*

Bisphosphonate Derivatives: Nonsteroidal Anti-Inflammatory Agents may enhance the adverse/toxic effect of Bisphosphonate Derivatives. Both an increased risk of gastrointestinal ulceration and an increased risk of nephrotoxicity are of concern. *Risk C: Monitor therapy*

Corticosteroids (Systemic): May enhance the adverse/toxic effect of NSAID (Nonselective). *Risk C: Monitor therapy*

CycloSPORINE: Nonsteroidal Anti-Inflammatory Agents may enhance the nephrotoxic effect of CycloSPORINE. Nonsteroidal Anti-Inflammatory Agents may increase the serum concentration of CycloSPORINE. *Risk D: Consider therapy modification*

CycloSPORINE, Systemic: Nonsteroidal Anti-Inflammatory Agents may enhance the nephrotoxic effect of CycloSPORINE, Systemic. Nonsteroidal Anti-Inflammatory Agents may increase the serum concentration of CycloSPORINE, Systemic. *Risk D: Consider therapy modification*

Dasatinib: May enhance the anticoagulant effect of Antiplatelet Agents. *Risk C: Monitor therapy*

Desmopressin: Nonsteroidal Anti-Inflammatory Agents may enhance the adverse/toxic effect of Desmopressin. *Risk C: Monitor therapy*

Drotrecogin Alfa: Antiplatelet Agents may enhance the adverse/toxic effect of Drotrecogin Alfa. Bleeding may occur. *Risk D: Consider therapy modification*

Eplerenone: Nonsteroidal Anti-Inflammatory Agents may diminish the antihypertensive effect of Eplerenone. Nonsteroidal Anti-Inflammatory Agents may enhance the hyperkalemic effect of Eplerenone. *Risk C: Monitor therapy*

Glucosamine: May enhance the antiplatelet effect of Antiplatelet Agents. *Risk C: Monitor therapy*

Herbs (Anticoagulant/Antiplatelet Properties) (eg, Alfalfa, Anise, Bilberry): May enhance the adverse/toxic effect of Antiplatelet Agents. Bleeding may occur. *Risk D: Consider therapy modification*

Herbs (Anticoagulant/Antiplatelet Properties) (eg, Alfalfa, Anise, Bilberry): May enhance the adverse/toxic effect of Nonsteroidal Anti-Inflammatory Agents. Bleeding may occur. *Risk D: Consider therapy modification*

HydrALAZINE: Nonsteroidal Anti-Inflammatory Agents may diminish the antihypertensive effect of HydrALAZINE. *Risk C: Monitor therapy*

Ibritumomab: Antiplatelet Agents may enhance the adverse/toxic effect of Ibritumomab. Both agents may contribute to impaired platelet function and an increased risk of bleeding. *Risk C: Monitor therapy*

Ketorolac: May enhance the adverse/toxic effect of Nonsteroidal Anti-Inflammatory Agents. *Risk X: Avoid combination*

Ketorolac, Systemic: May enhance the adverse/toxic effect of Nonsteroidal Anti-Inflammatory Agents. *Risk X: Avoid combination*

Lithium: Nonsteroidal Anti-Inflammatory Agents may increase the serum concentration of Lithium. *Risk D: Consider therapy modification*

Loop Diuretics: Nonsteroidal Anti-Inflammatory Agents may diminish the diuretic effect of Loop Diuretics. *Risk C: Monitor therapy*

Methotrexate: Nonsteroidal Anti-Inflammatory Agents may decrease the excretion of Methotrexate. *Risk D: Consider therapy modification*

Nonsteroidal Anti-Inflammatory Agents: May enhance the adverse/toxic effect of Antiplatelet Agents. An increased risk of bleeding may occur. Nonsteroidal Anti-Inflammatory Agents may diminish the cardioprotective effect of Antiplatelet Agents. This interaction is likely specific to aspirin, and not to other antiplatelet agents. *Risk C: Monitor therapy*

Nonsteroidal Anti-Inflammatory Agents: May enhance the adverse/toxic effect of other Nonsteroidal Anti-Inflammatory Agents. *Risk C: Monitor therapy*

Omega-3-Acid Ethyl Esters: May enhance the antiplatelet effect of Antiplatelet Agents. *Risk C: Monitor therapy*

Pemetrexed: NSAID (Nonselective) may increase the serum concentration of Pemetrexed. Management: Patients with mild-to-moderate renal insufficiency (CrCl 45-79 mL/minute) may

use ibuprofen with caution, but should avoid other NSAIDs for 2-5 days prior to, the day of, and 2 days after pemetrexed. *Risk D: Consider therapy modification*

Pentosan Polysulfate Sodium: May enhance the adverse/toxic effect of Antiplatelet Agents. Specifically, the risk of bleeding may be increased by concurrent use of these agents. *Risk C: Monitor therapy*

Pentoxifylline: May enhance the antiplatelet effect of Antiplatelet Agents. *Risk C: Monitor therapy*

Potassium-Sparing Diuretics: Nonsteroidal Anti-Inflammatory Agents may diminish the antihypertensive effect of Potassium-Sparing Diuretics. Nonsteroidal Anti-Inflammatory Agents may enhance the hyperkalemic effect of Potassium-Sparing Diuretics. *Risk C: Monitor therapy*

Pralatrexate: Nonsteroidal Anti-Inflammatory Agents may increase the serum concentration of Pralatrexate. More specifically, NSAIDS may decrease the renal excretion of pralatrexate. Management: Closely monitor for increased pralatrexate serum levels and/or toxicity if used concomitantly with an NSAID. Monitor for decreased pralatrexate serum levels with NSAID discontinuation. *Risk C: Monitor therapy*

Probenecid: May increase the serum concentration of Nonsteroidal Anti-Inflammatory Agents. *Risk C: Monitor therapy*

Prostacyclin Analogues: May enhance the antiplatelet effect of Antiplatelet Agents. *Risk C: Monitor therapy*

Quinolone Antibiotics: Nonsteroidal Anti-Inflammatory Agents may enhance the neuroexcitatory and/or seizure-potentiating effect of Quinolone Antibiotics. *Risk C: Monitor therapy*

Salicylates: NSAID (Nonselective) may enhance the adverse/toxic effect of Salicylates. An increased risk of bleeding may be associated with use of this combination. NSAID (Nonselective) may diminish the cardioprotective effect of Salicylates. Salicylates may decrease the serum concentration of NSAID (Nonselective). **Exceptions:** Choline Magnesium Trisalicylate. *Risk D: Consider therapy modification*

Salicylates: Antiplatelet Agents may enhance the adverse/toxic effect of Salicylates. Increased risk of bleeding may result. *Risk C: Monitor therapy*

Selective Serotonin Reuptake Inhibitors: May enhance the antiplatelet effect of NSAID (Nonselective). *Risk D: Consider therapy modification*

Serotonin/Norepinephrine Reuptake Inhibitors: May enhance the antiplatelet effect of NSAID (Nonselective). *Risk C: Monitor therapy*

Thiazide Diuretics: Nonsteroidal Anti-Inflammatory Agents may diminish the therapeutic effect of Thiazide Diuretics. *Risk C: Monitor therapy*

Thrombolytic Agents: Antiplatelet Agents may enhance the anticoagulant effect of Thrombolytic Agents. *Risk C: Monitor therapy*

Thrombolytic Agents: Nonsteroidal Anti-Inflammatory Agents may enhance the adverse/toxic effect of Thrombolytic Agents. An increased risk of bleeding may occur. *Risk C: Monitor therapy*

Tositumomab and Iodine I 131 Tositumomab: Antiplatelet Agents may enhance the adverse/toxic effect of Tositumomab and Iodine I 131 Tositumomab. Specifically, the risk of bleeding-related adverse events may be increased. *Risk C: Monitor therapy*

Treprostinil: May enhance the adverse/toxic effect of Nonsteroidal Anti-Inflammatory Agents. Bleeding may occur. *Risk C: Monitor therapy*

Vancomycin: Nonsteroidal Anti-Inflammatory Agents may decrease the excretion of Vancomycin. *Risk C: Monitor therapy*

Vitamin K Antagonists (eg, warfarin): NSAID (Nonselective) may enhance the anticoagulant effect of Vitamin K Antagonists. *Risk D: Consider therapy modification*

Ethanol/Nutrition/Herb Interactions

Ethanol: Avoid ethanol (may enhance gastric mucosal irritation).

Food: Naproxen absorption rate/levels may be decreased if taken with food.

Herb/Nutraceutical: Avoid alfalfa, anise, bilberry, bladderwrack, bromelain, cat's claw, celery, chamomile, coleus, cordyceps, dong quai, evening primrose, fenugreek, feverfew, garlic, ginger, ginkgo biloba, ginseng (American, Panax, Siberian), grapeseed, green tea, guggul, horse chestnut seed, horseradish, licorice, prickly ash, red clover, reishi, SAMe (S-adenosylmethionine), sweet clover, turmeric, white willow (all have additional antiplatelet activity).

Storage

Store oral suspension and tablet at 15°C to 30°C (59°F to 86°F).

Mechanism of Action

Reversibly inhibits cyclooxygenase-1 and 2 (COX-1 and 2) enzymes, which results in decreased formation of prostaglandin precursors; has antipyretic, analgesic, and anti-inflammatory properties

Other proposed mechanisms not fully elucidated (and possibly contributing to the anti-inflammatory effect to varying degrees), include inhibiting chemotaxis, altering lymphocyte activity, inhibiting neutrophil aggregation/activation, and decreasing proinflammatory cytokine levels.

Pharmacodynamics/Kinetics

Onset of action: Analgesic: 1 hour; Anti-inflammatory: ~2 weeks

Peak effect: Anti-inflammatory: 2-4 weeks

Duration: Analgesic: ?7 hours; Anti-inflammatory: ?12 hours

Absorption: Almost 100%

Distribution: 0.16 L/kg

Protein binding: >99% to albumin; increased free fraction in elderly

Metabolism: Hepatic to metabolites

Bioavailability: 95%

Half-life elimination: Normal renal function: 12-17 hours; End-stage renal disease: No change

Time to peak, serum: 1-4 hours

Excretion: Urine (95%; primarily as metabolites); feces (?3%)

Dosage

Note: Dosage expressed as naproxen base; 200 mg naproxen base is equivalent to 220 mg naproxen sodium.

Oral:

Children >2 years: Juvenile arthritis: 10 mg/kg/day in 2 divided doses

Adults:

Gout, acute: Initial: 750 mg, followed by 250 mg every 8 hours until attack subsides. **Note:** EC-Naprosyn® is not recommended.

Migraine, acute (unlabeled use): Initial: 500-750 mg; an additional 250-500 mg may be given if needed (maximum: 1250 mg in 24 hours). **Note:** EC-Naprosyn® is not recommended.

Pain (mild-to-moderate), dysmenorrhea, acute tendonitis, bursitis: Initial: 500 mg, then 250 mg every 6-8 hours; maximum: 1250 mg/day naproxen base

Rheumatoid arthritis, osteoarthritis, and ankylosing spondylitis: 500-1000 mg/day in 2 divided doses; may increase to 1.5 g/day of naproxen base for limited time period

OTC labeling: Pain/fever:

Children ?12 years and Adults ?65 years: 200 mg naproxen base every 8-12 hours; if needed, may take 400 mg naproxen base for the initial dose; maximum: 600 mg naproxen base/24 hours

Adults >65 years: 200 mg naproxen base every 12 hours

Dosing adjustment in renal impairment: Cl_{cr} <30 mL/minute: use is not recommended

Dental Usual Dosing

Mild-to-moderate pain: Adults: Initial: 500 mg, then 250 mg every 6-8 hours; maximum: 1250 mg/day naproxen base

Pain/fever (OTC labeling):

Children ?12 years and Adults ?65 years: 200 mg naproxen base every 8-12 hours; if needed, may take 400 mg naproxen base for the initial dose; maximum: 600 mg naproxen base/24 hours

Adults >65 years: 200 mg naproxen base every 12 hours

Administration: Oral

Administer with food, milk, or antacids to decrease GI adverse effects

Suspension: Shake suspension well before administration.

Tablet, extended release: Swallow tablet whole; do not break, crush, or chew.

Monitoring Parameters

Occult blood loss, periodic liver function test, CBC, BUN, serum creatinine; urine output

Test Interactions

Naproxen may interfere with 5-HIAA urinary assays; due to an interaction with m-dinitrobenzene, naproxen should be discontinued 72 hours before adrenal function testing if the Porter-Silber test is used.

Dietary Considerations

Drug may cause GI upset, bleeding, ulceration, perforation; take with food or milk to minimize GI upset.

Patient Education

Take this medication exactly as directed; do not increase dose without consulting prescriber. Do not crush tablets. Take with food or milk to reduce GI distress. Maintain adequate hydration unless instructed to restrict fluid intake. Do not use alcohol, aspirin or aspirin-containing medication, or any other anti-inflammatory medications without consulting prescriber. You may experience drowsiness, dizziness, lightheadedness, or headache (use caution when driving or engaging in tasks requiring alertness until response to drug is known); anorexia, nausea, vomiting, or heartburn (small frequent meals, frequent mouth care, sucking lozenges, or chewing gum may help); or fluid retention (weigh yourself weekly and report unusual [3-5 lb/week] weight gain), GI bleeding, ulceration, or perforation can occur with or without pain; or discontinue medication and contact prescriber if persistent abdominal pain or cramping, or blood in stool occurs. Report breathlessness, respiratory difficulty, or unusual cough; chest pain, rapid heartbeat, palpitations; unusual bruising/bleeding; blood in urine, stool, mouth, or vomitus; swollen extremities; skin rash or itching; acute fatigue; or changes in eyesight (double vision, color changes, blurred vision), hearing, or ringing in ears.
Pregnancy/breast-feeding precautions: Notify prescriber if you are or intend to become pregnant. Do not take this drug during last trimester of pregnancy. Consult prescriber if breast-feeding.

Geriatric Considerations

Elderly are a high-risk population for adverse effects from NSAIDs. As much as 60% of the elderly can develop peptic ulceration and/or hemorrhage asymptomatically. The concomitant use of H_2 blockers and sucralfate is not effective as prophylaxis with the exception of NSAID-induced duodenal ulcers which may be prevented by the use of ranitidine. Misoprostol and proton pump inhibitors are the only agents proven to help prevent the development of NSAID-induced ulcers. Also, concomitant disease and drug use contribute to the risk for GI adverse effects. Use lowest effective dose for shortest period possible. Consider renal function decline with age. Use of NSAIDs can compromise existing renal function especially when Cl_{cr} is ?30 mL/minute. Tinnitus may be a difficult and unreliable indication of toxicity due to age-related hearing loss or eighth cranial nerve damage. CNS adverse effects such as confusion, agitation, and hallucination are generally seen in overdose or high-dose situations, but elderly may demonstrate these adverse effects at lower doses than younger adults.

Anesthesia and Critical Care Concerns/Other Considerations

The 2002 ACCM/SCCM guidelines for analgesia (critically-ill adult) suggest that NSAIDs may be used in combination with opioids in select patients for pain management. Concern about adverse events (increased risk of renal dysfunction, altered platelet function and gastrointestinal irritation) limits its use in patients who have other underlying risks for these events.

In short-term use, NSAIDs vary considerably in their effect on blood pressure. When NSAIDs are used in patients with hypertension, appropriate monitoring of blood pressure responses should be completed and the duration of therapy, when possible, kept short. The use of NSAIDs in the treatment of patients with congestive heart failure may be associated with an increased risk for fluid accumulation and edema; may precipitate renal failure in dehydrated patients. Should not be used to treat perioperative pain after coronary bypass surgery (CABG).

Cardiovascular Considerations

Blood Pressure: In short-term use, NSAIDs vary considerably in their effect on blood pressure. A meta-analysis (Pope, 1993) showed that indomethacin and naproxen had the largest effect on blood pressure. Other NSAIDs, including piroxicam, ibuprofen, and sulindac had less of an effect. Ibuprofen combined with captopril or losartan may attenuate the antihypertensive effects of ACE inhibition or receptor blockade on sitting or 24-hour ambulatory diastolic blood pressure. When NSAIDs are used in patients with hypertension, appropriate monitoring of blood pressure responses should be completed and the duration of therapy, when possible, kept short.

Heart Failure: The use of NSAIDs in the treatment of patients with heart failure may be

associated with an increased risk for fluid accumulation and edema. One study showed that NSAID use in elderly patients had an increased risk of hospitalization for heart failure. This study gives compelling reasons to avoid or limit the use of NSAIDs in patients with heart failure, particularly in the elderly population. The ACC/AHA 2009 heart failure guidelines suggest that NSAIDs be avoided or withdrawn whenever possible in patients with current or prior symptoms of heart failure and reduced LVEF.

Risk of Cardiovascular Events: Patients at increased risk of cardiovascular adverse events include patients immediately postoperative (10-14 days) from CABG surgery, and those with existing CAD, CVD, or history of TIA. Prescribers are encouraged to use the lowest effective dose for the shortest duration of time based on individual patient treatment goals. Available evidence reviewed by the FDA does not suggest an increased risk of serious CV events when NSAIDs are given short term and in the lower doses used OTC.

Drug Interactions: Nonsteroidal anti-inflammatory agents, including ibuprofen and naproxen, may diminish the cardioprotective effect of aspirin (Catella-Lawson F, 2001; Capone ML, 2005). It is surmised that ibuprofen may exhibit greater affinity than aspirin for the COX-1 site or if dosed regularly (or prior to aspirin), it would gain access to the active site first. In either case, aspirin's inhibition of COX (irreversible) would be limited in favor of ibuprofen inhibition (reversible). Avoid regular use of NSAIDs (nonselective) if possible. If used occasionally, take after aspirin (immediate release) ingestion.

Dental Health: Effects on Dental Treatment

Key adverse event(s) related to dental treatment: Stomatitis.

Naproxen and naproxen sodium have the potential to interfere with the antiplatelet effect of low-dose aspirin. One study of naproxen and low-dose aspirin has suggested that naproxen may interfere with aspirin's antiplatelet activity when they are coadministered (Steinhubl, 2005). However, naproxen 500 mg administered 2 hours before or after aspirin 100 mg did not interfere with aspirin's antiplatelet effect. The FDA stated that there is no data looking at doses of naproxen <500 mg. Naproxen over-the-counter strength is 220 mg tablets.

The FDA has warned that ibuprofen can interfere with the antiplatelet effect of low-dose aspirin (81 mg/day), potentially rendering aspirin less effective when used for cardioprotection and stroke protection. In situations where these drugs could be used concomitantly, the FDA has proved the following information: Patients who use immediate release aspirin (not enteric-coated aspirin) and take single doses of ibuprofen 400 mg, should dose the ibuprofen at least 30 minutes or longer after aspirin ingestion or more than 8 hours before aspirin ingestion to avoid attenuation of aspirin's effect. Similar recommendations may hold for concomitant may hold for concomitant naproxen and aspirin use. See Effects on Bleeding.

Dental Health: Vasoconstrictor/Local Anesthetic Precautions

No information available to require special precautions

Mental Health: Effects on Mental Status

Dizziness is common; may cause nervousness; may rarely cause drowsiness, confusion, insomnia, depression, or hallucinations

Mental Health: Effects on Psychiatric Treatment

May rarely cause agranulocytosis; use caution with clozapine and carbamazepine; may decrease lithium clearance resulting in an increase in serum lithium levels and potential lithium toxicity; monitor serum lithium levels

Nursing: Physical Assessment/Monitoring

Evaluate cardiac risk and potential for GI bleeding prior to prescribing this medication. Assess effectiveness and interactions of other medications patient may be taking. Monitor blood pressure at the beginning of therapy and periodically during use. Assess results of laboratory tests, therapeutic effectiveness, and adverse reactions (eg, GI effects,

hepatotoxicity, or ototoxicity) at beginning of therapy and periodically throughout therapy. Schedule ophthalmic evaluations for patients who develop eye complaints during long-term NSAID therapy. Assess knowledge/teach patient appropriate use, interventions to reduce side effects, and adverse symptoms to report.

Dosage Forms

Excipient information presented when available (limited, particularly for generics); consult specific product labeling. [DSC] = Discontinued product

Caplet, as sodium: 220 mg [equivalent to naproxen 200 mg and sodium 20 mg]

Aleve®, Midol® Extended Relief, Pamprin® Maximum Strength All Day Relief: 220 mg [equivalent to naproxen 200 mg and sodium 20 mg]

Capsule, liquid gel, as sodium:

Aleve®: 220 mg [equivalent to naproxen 200 mg and sodium 20 mg]

Combination package, oral [dose-pack]:

Naprelan® [each package contains]:

Day 1-3: Tablet, controlled release, oral, as sodium: 825 mg (6s) [equivalent to naproxen base 750 mg and sodium 75 mg]

Day 4-10: Tablet, controlled release, oral, as sodium: 550 mg (14s) [equivalent to naproxen base 500 mg and sodium 50 mg]

Gelcap, as sodium:

Aleve®: 220 mg [equivalent to naproxen 200 mg and sodium 20 mg]

Suspension, oral: 125 mg/5 mL (500 mL)

Naprosyn®: 125 mg/5 mL (473 mL) [contains sodium 39 mg (1.5 mEq)/5 mL; orange-pineapple flavor]

Tablet: 250 mg, 375 mg, 500 mg

Naprosyn®: 250 mg, 375 mg, 500 mg

Tablet, as sodium: 220 mg [equivalent to naproxen 200 mg and sodium 20 mg]; 275 mg [equivalent to naproxen 250 mg and sodium 25 mg]; 550 mg [equivalent to naproxen 500 mg and sodium 50 mg]

Aleve®: 220 mg [equivalent to naproxen 200 mg and sodium 20 mg]

Anaprox®: 275 mg [equivalent to naproxen 250 mg and sodium 25 mg]

Anaprox® DS: 550 mg [equivalent to naproxen 500 mg and sodium 50 mg]

Mediproxen: 220 mg [equivalent to naproxen 200 mg and sodium 20 mg]

Tablet, controlled release, as sodium:

Naprelan®: 412.5 mg [equivalent to naproxen 375 mg and sodium 37.5 mg]

Naprelan®: 550 mg [equivalent to naproxen 500 mg and sodium 50 mg]

Naprelan®: 825 mg [equivalent to naproxen 750 mg and sodium 75 mg]

Tablet, delayed release, enteric coated: 375 mg, 500 mg

EC-Naprosyn®: 375 mg, 500 mg

Tablet, extended release, as sodium: 550 mg [equivalent to naproxen 500 mg and sodium 50 mg] [DSC]

Pricing: U.S. (www.drugstore.com)

Suspension (Naprosyn)

125 mg/5 mL (300): $47.25

Suspension (Naproxen)

125 mg/5 mL (500): $51.50

Tablet, 24-hour (Naprelan)

375 mg (30): $104.99

500 mg (30): $108.80

750 mg (30): $195.27

Tablet, EC (EC-Naprosyn)

375 mg (30): $54.94

500 mg (30): $60.44

Tablet, EC (Naproxen DR)

375 mg (60): $35.99

500 mg (60): $64.99

Tablets (Anaprox)

275 mg (30): $70.76

Tablets (Anaprox DS)

550 mg (30): $96.04

Tablets (Naprosyn)

375 mg (100): $157.14

500 mg (30): $65.93

Tablets (Naproxen)

250 mg (90): $16.00

375 mg (90): $17.00

500 mg (60): $17.99

Tablets (Naproxen Sodium)

275 mg (60): $15.99

550 mg (30): $14.99

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International Brand Names

- Acusprain (ZA)
- Aflamax (PE)
- Aleve (AU, EE, PL, PY, SG, UY)
- Alpron (PH)
- Anapran (PL)
- Anexopen (GR)
- Antalgin (ES)
- Apo-Naproxen (PL)
- Apranax (BG, CR, DO, FR, GT, HN, NI, PA, PL, RU, SV, VE)
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- Boloxen (PL)
- Bonyl (DK)
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