NAPROSYN®

NAPROXEN ORAL SUSPENSION USP
(125 mg/5 mL)

RX Only

NAPROSYN® Oral Suspension
Non-Steroidal Anti-Inflammatory Drug

INDICATIONS & USAGE

THE RELIEF OF THE SIGNS AND SYMPTOMS OF:

- Rheumatoid Arthritis
- Osteoarthritis
- Polyarticular Juvenile Idiopathic Arthritis
- Acute Gout
- Bursitis
- Tendonitis
- Ankylosing Spondylitis

THE MANAGEMENT OF:

- Pain
- Primary Dysmenorrhea

These highlights do not include all the information needed to use NAPROSYN (naproxen) SUSPENSION safely and effectively. See full prescribing information for NAPROSYN SUSPENSION.

IMPORTANT SAFETY INFORMATION

WARNING: RISK OF SERIOUS CARDIOVASCULAR AND GASTROINTESTINAL EVENTS

See full prescribing information for complete boxed warning.

- Nonsteroidal anti-inflammatory drugs (NSAIDs) cause an increased risk of serious cardiovascular thrombotic events, including myocardial infarction and stroke, which can be fatal. This risk may occur early in treatment and may increase with duration of use. (5.1) - *See Section 5.1 of the Full Prescribing Information.*
- NAPROSYN Suspension is contraindicated in the setting of coronary artery bypass graft (CABG) surgery. (4, 5.1)
- NSAIDs cause an increased risk of serious gastrointestinal (GI) adverse events including bleeding, ulceration, and perforation of the stomach or intestines, which can be fatal. These events can occur at any time during use and without warning symptoms. Elderly patients and patients with a prior history of peptic ulcer disease and/or GI bleeding are at greater risk for serious GI events. (5.2)

DOSAGE AND ADMINISTRATION

Use the lowest effective dose for shortest duration consistent with individual patient treatment goals. (2) - See Section 2 of the Full Prescribing Information.

Rheumatoid Arthritis, Osteoarthritis, and Ankylosing Spondylitis (2)

NAPROSYN® Oral Suspension	250 mg (10 mL)	twice daily
	or 375 mg (15 mL)	twice daily
	or 500 mg (20 mL)	twice daily

Polyarticular Juvenile Idiopathic Arthritis

The dose may be adjusted up or down depending on the clinical response of the patient. In patients who tolerate lower doses well, the dose may be increased to naproxen 1500 mg/day for up to 6 months. (2)

Recommended total daily dose of naproxen is approximately 10 mg/kg given in 2 divided doses. (2)
The following table may be used as a guide for dosing of naproxen suspension: (2)

Patients Weight	Dose	Administered as
13 kg (29 lb)	62.5 mg twice daily	2.5 mL (1/2 tsp) twice daily
25 kg (55 lb)	125 mg twice daily	5.0 mL (1 tsp) twice daily
38 kg (84 lb)	187.5 mg twice daily	7.5 mL ($1^{1/2}$ tsp) twice daily

Management of Pain, Primary Dysmenorrhea, and Acute Tendonitis and Bursitis

The recommended starting dose of NAPROSYN Suspension is 500 mg (20 mL), followed by 250 mg (10 mL) every 6 to 8 hours as required. (2)

Acute Gout

The recommended starting dose is 750 mg (30 mL) of NAPROSYN Suspension followed by 250 mg (10 mL) every 8 hours until the attack has subsided. (2)

DOSAGE FORMS AND STRENGTHS

NAPROSYN Suspension: 125 mg/5 mL (contains 39 mg sodium) (3)

CONTRAINDICATIONS

- Known hypersensitivity to naproxen or any components of the drug product (4)
- History of asthma, urticaria, or other allergic-type reactions after taking aspirin or other NSAIDs (4)
- In the setting of CABG surgery (4)

WARNINGS AND PRECAUTIONS

Hepatotoxicity: Inform patients of warning signs and symptoms of hepatotoxicity. Discontinue if abnormal liver tests persist or worsen or if clinical signs and symptoms of liver disease develop. (5.3) (5)
Hypertension: Patients taking some antihypertensive medications may have impaired response to these therapies when taking NSAIDs. Monitor blood pressure. (5.4, 7) (5)
Heart Failure and Edema: Avoid use of NAPROSYN Suspension in patients with severe heart failure unless benefits are expected to outweigh risk of worsening heart failure. (5.5) (5)
Renal Toxicity: Monitor renal function in patients with renal or hepatic impairment, heart failure, dehydration, or hypovolemia. Avoid use of NAPROSYN Suspension in patients with advanced renal disease unless benefits are expected to outweigh risk of worsening renal function. (5.6) (5)
Anaphylactic Reactions: Seek emergency help if an anaphylactic reaction occurs. (5.7) (5)
Exacerbation of Asthma Related to Aspirin Sensitivity: NAPROSYN Suspension is contraindicated in patients with aspirin-sensitive asthma. Monitor patients with preexisting asthma (without aspirin sensitivity). (5.8) (5)
Serious Skin Reactions: Discontinue NAPROSYN Suspension at first appearance of skin rash or other signs of hypersensitivity. (5.9) (5)
Premature Closure of Fetal Ductus Arteriosus: Avoid use in pregnant women starting at 30 weeks gestation. (5.10, 8.1) (5)
Hematologic Toxicity: Monitor hemoglobin or hematocrit in patients with any signs or symptoms of anemia. (5.11,7) (5)

ADVERSE REACTIONS

Most common adverse reactions to naproxen were dyspepsia, abdominal pain, nausea, headache, rash, ecchymosis, and edema. (6.1) (6)

To report SUSPECTED ADVERSE REACTIONS, contact Athena Bioscience LLC at 1-833-284-3622 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch. (6)

DRUG INTERACTIONS

Drugs that Interfere with Hemostasis (e.g. warfarin, aspirin, SSRIs/SNRIs): Monitor patients for bleeding who are concomitantly taking NAPROSYN Suspension with drugs that interfere with hemostasis. Concomitant use of NAPROSYN Suspension and analgesic doses of aspirin is not generally recommended. (7)
ACE inhibitors, Angiotensin Receptor Blockers (ARB), or Beta-Blockers: Concomitant use with NAPROSYN Suspension may diminish the antihypertensive effect of these drugs. Monitor blood pressure. (7)
ACE Inhibitors and ARBs: Concomitant use with NAPROSYN Suspension in elderly, volume depleted, or those with renal impairment may result in deterioration of renal function. In such high risk patients, monitor for signs of worsening renal function. (7)
Diuretics: NSAIDs can reduce natriuretic effect of furosemide and thiazide diuretics. Monitor patients to assure diuretic efficacy including antihypertensive effects. (7)
Digoxin: Concomitant use with NAPROSYN Suspension can increase serum concentration and prolong half-life of digoxin. Monitor serum digoxin levels. (7)

USE IN SPECIFIC POPULATIONS

Pregnancy: Use of NSAIDs during the third trimester of pregnancy increases the risk of premature closure of the fetal ductus arteriosus. Avoid use of NSAIDs in pregnant women starting at 30 weeks gestation. (5.10, 8.1) (8)
Infertility: NSAIDs are associated with reversible infertility. Consider withdrawal of NAPROSYN Suspension in women who have difficulties conceiving. (8.3) (8)
Renal Impairment: Naproxen-containing products are not recommended for use in patients with moderate to severe and severe renal impairment (creatinine clearance <30 mL/min). (8.7) (8)

Please refer to full prescribing information, including Medication Guide and Complete Boxed Warning, before prescribing.

FOR ADDITIONAL INFORMATION, VISIT www.athenabioscience.com OR CALL (833) 284-3622

ATHENA BIOSCIENCE

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