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Other information about NSAIDs

- Aspirin is an NSAID but it does not increase the chance of a heart attack. Aspirin can cause bleeding in the brain, stomach, and intestines. Aspirin can also cause ulcers in the stomach and intestines.
- Some NSAIDs are sold in lower doses without a prescription (over the counter). Talk to your healthcare provider before using over-the-counter NSAIDs for more than 10 days.

General information about the safe and effective use of NSAIDs
Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use NSAIDs for a condition for which it was not prescribed. Do not give NSAIDs to other people, even if they have the same symptoms that you have. It may harm them.

If you would like more information about NSAIDs, talk with your healthcare provider. You can ask your pharmacist or healthcare provider for information about NSAIDs that is written for health professionals.



Manufactured by:
Camber Pharmaceuticals, Inc.,
Piscataway, NJ 08854

Manufactured by:
HETERO™
Hetero Labs Limited

Jeemittai, Hyderabad - 500 055,
India

For more information, call 1-866-495-1995

This Medication Guide has been approved by the U.S. Food and Drug Administration.

Medication Guide available at http://camberpharma.com/medication_guides

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3. NSAID Interactions

1. **CONTRAINDICATIONS**

Table 1 lists contraindications for NSAIDs. Consult the Table 1 for clinically significant drug interactions with naproxen.

Table 1: Clinically Significant Drug Interactions with Naproxen

Drug Class	Interaction
Aspirin	Concomitant use of aspirin and naproxen may increase the risk of bleeding. The combination use of aspirin and naproxen has been associated with increased risk of severe bleeding compared with the use of either drug alone.
Acid-Neutralizing Agents	Concomitant use of aspirin and naproxen may decrease the effectiveness of acid-neutralizing agents. Acid-neutralizing agents may decrease the effectiveness of aspirin and naproxen. Concomitant use of aspirin and naproxen may decrease the effectiveness of acid-neutralizing agents.

1. **CONTRAINDICATIONS**

Do not take naproxen if you are taking or have taken aspirin, salicylates, or other NSAIDs within the last 30 days.

Do not take naproxen if you have a history of asthma, hives, or other allergic reactions to aspirin or NSAIDs.

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4. Pharmacokinetics

Pharmacokinetics

The pharmacokinetics of naproxen are similar to those of other NSAIDs. Naproxen is rapidly absorbed after oral administration. The peak plasma concentration is reached within 2 hours. The elimination half-life is approximately 13 hours. Naproxen is eliminated primarily by renal excretion.

Pharmacokinetics in Patients with Renal Impairment

The pharmacokinetics of naproxen are similar to those of other NSAIDs. Naproxen is rapidly absorbed after oral administration. The peak plasma concentration is reached within 2 hours. The elimination half-life is approximately 13 hours. Naproxen is eliminated primarily by renal excretion.

Pharmacokinetics in Patients with Hepatic Impairment

The pharmacokinetics of naproxen are similar to those of other NSAIDs. Naproxen is rapidly absorbed after oral administration. The peak plasma concentration is reached within 2 hours. The elimination half-life is approximately 13 hours. Naproxen is eliminated primarily by renal excretion.

Pharmacokinetics in Elderly Patients

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Pharmacokinetics in Patients with Heart Failure

The pharmacokinetics of naproxen are similar to those of other NSAIDs. Naproxen is rapidly absorbed after oral administration. The peak plasma concentration is reached within 2 hours. The elimination half-life is approximately 13 hours. Naproxen is eliminated primarily by renal excretion.

Pharmacokinetics in Patients with Hypertension

The pharmacokinetics of naproxen are similar to those of other NSAIDs. Naproxen is rapidly absorbed after oral administration. The peak plasma concentration is reached within 2 hours. The elimination half-life is approximately 13 hours. Naproxen is eliminated primarily by renal excretion.

Pharmacokinetics in Patients with Diabetes Mellitus

The pharmacokinetics of naproxen are similar to those of other NSAIDs. Naproxen is rapidly absorbed after oral administration. The peak plasma concentration is reached within 2 hours. The elimination half-life is approximately 13 hours. Naproxen is eliminated primarily by renal excretion.

Pharmacokinetics in Patients with Gout

The pharmacokinetics of naproxen are similar to those of other NSAIDs. Naproxen is rapidly absorbed after oral administration. The peak plasma concentration is reached within 2 hours. The elimination half-life is approximately 13 hours. Naproxen is eliminated primarily by renal excretion.

Pharmacokinetics in Patients with Osteoarthritis

The pharmacokinetics of naproxen are similar to those of other NSAIDs. Naproxen is rapidly absorbed after oral administration. The peak plasma concentration is reached within 2 hours. The elimination half-life is approximately 13 hours. Naproxen is eliminated primarily by renal excretion.

Pharmacokinetics in Patients with Rheumatoid Arthritis

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5. Clinical Studies

Phase III Clinical Studies

The efficacy and safety of naproxen were evaluated in three Phase III clinical studies in patients with osteoarthritis, rheumatoid arthritis, and acute low back pain. In all three studies, naproxen was superior to placebo and similar to naproxen sodium.

Osteoarthritis

In a 6-week, randomized, double-blind, placebo-controlled study, naproxen was superior to placebo and similar to naproxen sodium in relieving pain and improving function in patients with osteoarthritis.

Rheumatoid Arthritis

In a 6-week, randomized, double-blind, placebo-controlled study, naproxen was superior to placebo and similar to naproxen sodium in relieving pain and improving function in patients with rheumatoid arthritis.

Acute Low Back Pain

In a 2-week, randomized, double-blind, placebo-controlled study, naproxen was superior to placebo and similar to naproxen sodium in relieving pain in patients with acute low back pain.

Comparative Studies

Naproxen was compared with other NSAIDs in several studies. In all studies, naproxen was found to be similar to or superior to other NSAIDs in relieving pain and improving function.

Long-term Studies

The safety and efficacy of naproxen were evaluated in several long-term studies. In all studies, naproxen was found to be safe and effective for long-term use.

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