

Naproxen - Patient Information Sheet

This is a summary of the most important information about naproxen. For details, talk to your healthcare provider.

FDA Alert [12/23/04]: Based on emerging information, the risk of cardiovascular and cerebrovascular events may increase among patients taking naproxen. FDA recommends patients not exceed the recommended dose. For more information about these risks, refer to the FDA Alert for Healthcare Providers.

What Is Naproxen?

Naproxen is a non-steroidal anti-inflammatory drug (NSAID) used as a pain reliever/fever reducer.

It is available over the counter for:

- Headache
- Minor pain of arthritis
- Backaches
- Menstrual cramps
- Muscular aches
- Toothaches
- The common cold
- Temporary reducing fever

And by prescription for:

- Relief of symptoms of osteoarthritis (the arthritis caused by age-related wear and tear on bones and joints), rheumatoid arthritis in adults, and juvenile arthritis
- Relief of signs and symptoms of ankylosing spondylitis
- Reducing swelling and relieving pain caused by gout
- Relieving the signs and symptoms of tendonitis and bursitis

Who Should Not Take Naproxen?

Do not take naproxen if you:

- Ever had asthma, rhinitis, or nasal polyps after taking aspirin
 or other NSAID medicines. Aspirin-sensitive patients should
 not take naproxen as reactions have the potential of causing
 death.
- Have advanced kidney disease
- Are pregnant, especially your last 3 months.

What Should I Do Before Taking Naproxen?

Ask a doctor or pharmacist before using naproxen if you:

- Are trying to get pregnant, are pregnant, or are breast-feeding
- Have or had angina (chest pain), heart attack, or blocked artery in your heart
- Have kidney problems
- Have liver problems
- Have heart failure
- Have high blood pressure
- Retain fluids (hold extra body water and swell)
- Had an allergic reaction to aspirin or other NSAID medicines
- Had a serious stomach problem in the past
- Have or had any other medical problems or allergies

Does Naproxen Interact with other Drugs or Food?

Tell your healthcare provider about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements. Your healthcare provider may have to adjust your dose or watch you more closely if you take any of the following medications:

- Certain blood pressure medicines called ACE inhibitors
- Furosemide (Lasix)
- Lithium
- Methotrexate
- Warfarin (coumadin)
- Aspirin
- Other NSAIDs

Are There Other Risks?

Naproxen can cause stomach ulcers that bleed. The chance of this serious problem increases the longer you take naproxen and with higher doses of naproxen. Stomach bleeding can also happen suddenly while you take naproxen. Stop taking naproxen and call your healthcare provider right away if you get:

- A burning stomach pain
- Black bowel movements that look like tar
- Vomit that looks like blood or coffee grounds

Allergic reactions: Naproxen can cause serious allergic reactions, including asthma-like symptoms (problems breathing, swallowing, and wheezing) and rash.

Liver damage: Stop taking naproxen and tell your doctor right away if you have nausea, vomiting, tiredness, loss of appetite, itching, yellow coloring of skin or eyes, flu-like symptoms, and dark urine.

Kidney problems: Naproxen can cause serious kidney problems, including sudden kidney failure or worsening of kidney problems that you already have.

Fluid retention: Naproxen can cause fluid retention (holding of water in your body) and swelling. Fluid retention can be a serious problem if you have high blood pressure or heart failure.

Pregnancy: Do not take naproxen during your last 3 months of pregnancy because it may cause problems in the unborn child or complications during delivery. Tell your doctor if you are pregnant or planning to become pregnant

Breast-feeding: Tell your doctor if you are breast-feeding.

How Do I Take Naproxen?

When taking an over-the-counter naproxen product, 1 tablet (220 mg) should be taken every 8 to 12 hours while symptoms last. You may take 2 tablets within the first hour of symptoms for the first dose. However, you should not exceed 2 tablets (440 mg) in any 8 to 12 hour period or 3 tablets (660 mg) in a 24-hour period. If your healthcare provider has prescribed naproxen to you, you should take it according to their directions.

FDA Naproxen Approval: 1976 Patient Information Sheet Revised: 12/23/2004

