Naproxen is used to relieve pain and swelling (inflammation) from various conditions. It is used to treat headaches, muscle aches, backaches, tendonitis, dental pain, and menstrual cramps. It also reduces pain, swelling, and joint stiffness caused by arthritis, bursitis, and gout attacks. Reducing these symptoms helps you do more of your normal daily activities.



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# Systematic (IUPAC) name

(+)-(S)-2-(6-methoxynaphthalen-2-yl) propanoic acid

## **Identifiers**

ATC code G02CC02 M01AE02, M02AA12 PubChem 1302 DrugBank APRD01135 ChemSpider 137720

# **Chemical data**

Formula C14H14O3 Mol. mass 230.259 g/mol

## Pharmacokinetic data

Bioavailability 95% (oral) Protein binding 99%

Metabolism Hepatic (to 6-desmethylnaproxen)

Half life 12–24 hours Excretion Renal

Naproxenis a non-steroidal anti-inflammatory drug (NSAID) commonly used for the reduction of moderate to severe pain, fever, inflammation and stiffness caused by conditions such as osteoarthritis, rheumatoid arthritis, psoriatic arthritis, gout, ankylosing spondylitis, menstrual cramps, tendinitis, bursitis, and the treatment of primary dysmenorrhea.

# WARNING

This drug may infrequently cause serious (rarely fatal) bleeding from the stomach or intestines. This side effect can occur without warning at any time during treatment with naproxen. The elderly are at increased risk for serious stomach/intestinal bleeding.

Drugs related to naproxen have rarely caused blood clots to form, resulting in serious (possibly fatal) heart attacks and strokes. This medication might also rarely cause similar problems. The risk of these serious side effects may increase if you have heart disease and with longer use of this medication. Talk to your doctor or pharmacist about the benefits and risks of treatment, as well as other possible medication choices.

Stop taking naproxen and seek immediate medical attention if you notice any of the following rare but very serious side effects: black stools, persistent stomach/abdominal pain, vomit that looks like coffee grounds, chest pain, shortness of breath, weakness on one side of the body, sudden vision changes, slurred speech. This medication should not be used right before or after heart bypass surgery.

#### **USES**

Naproxen is used to relieve pain and swelling (inflammation) from various conditions. It is used to treat headaches, muscle aches, backaches, tendonitis, dental pain, and menstrual cramps. It also reduces pain, swelling, and joint stiffness caused by arthritis, bursitis, and gout attacks. Reducing these symptoms helps you do more of your normal daily activities. This medication is known as a nonsteroidal anti-inflammatory drug

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CAS No 22204-53-1

HOW TO USE

Take this medication by mouth with a full glass of water (8 ounces or 240 milliliters) unless your doctor directs you otherwise. Do not lie down for at least 30 minutes after taking this drug. To prevent stomach upset, take this medication with food, milk, or an antacid.

Dosage is based on your medical condition and response to therapy. Do not take more than 1,500 milligrams of naproxen (equal to 1,650 milligrams of naproxen sodium) per day. To minimize side effect risks (e.g., stomach bleeding), use this medication at the lowest effective dose for the shortest possible length of time. Do not increase your dose or take it more often than prescribed. For ongoing conditions such as arthritis, continue taking it as directed by your doctor. Discuss the risks and benefits with your doctor or pharmacist.

In certain conditions (e.g., arthritis), it may take up to 2 weeks of regular use before the full benefits of this drug take effect.

# SIDE EFFECTS

Upset stomach, nausea, heartburn, diarrhea, constipation, headache, tiredness, drowsiness, and dizziness may occur. If any of these effects persist or worsen, notify your doctor or pharmacist promptly. Tell your doctor immediately if any of these unlikely but serious side effects occur: stomach pain, difficult/painful swallowing, swelling of the hands/feet, sudden/unexplained weight gain, vision changes, hearing changes (e.g., ringing in the ears), mental/mood changes (e.g., depression), fast/pounding heartbeat, persistent/severe headache, fainting. A very serious allergic reaction to this drug is unlikely, but seek immediate medical attention if it occurs. Symptoms of a serious allergic reaction may include: rash, itching, swelling, severe dizziness, trouble breathing.

# PRECAUTIONS

This medication should not be used if you have certain medical conditions. Before using this medicine, consult your doctor or pharmacist if you have: aspirin-sensitive asthma (a history of worsening breathing with runny/stuffy nose after taking aspirin or other NSAIDs), severe kidney disease, recent heart bypass surgery

Before using this medication, tell your doctor or pharmacist your medical history, especially of: kidney disease, liver disease, poorly controlled diabetes, stomach/intestine/esophagus problems (e.g., bleeding, ulcers), heart disease (e.g., congestive heart failure, history of heart attack), high blood pressure, stroke, swelling (edema, fluid retention), a severe loss of body water (dehydration), blood disorders (e.g., anemia), bleeding or clotting problems, asthma, growths in the nose (nasal polyps).

Some naproxen products contain salt (sodium). Tell your doctor if you are on a salt-restricted diet.

# **MISSED DOSE**

If you are prescribed this drug on a regular schedule (not just "as needed") and you miss a dose, take it as soon as you remember. If it is near the time of the next dose, skip the missed dose and resume your usual dosing schedule. Do not double the dose to catch up.

# STORAGE

Store at room temperature between 59-86 degrees F (15-30 degrees C) away from light and moisture. Do not store in the bathroom. Keep all medicines away from children and pets.

#### DOSAGE

Take naproxen exactly as directed on the label, or as it has been prescribed by your doctor. Do not use the medication in larger amounts, or use it for longer than recommended.



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Taj Pharmaceuticals Ltd.NaproxenImage: Cas No. : 22204-53-1Cas No. : 22204-53-1Image: Cas No. : 22204-53-1

Naprosyn is a slower-acting form of naproxen and this brand should be used only for treating arthritis or ankylosing spondylitis. Follow your doctors instructions.

Do not crush, chew, or break an extended-release or enteric-coated tablet. Swallow the pill whole. The extended-release pill is specially made to release medicine slowly in the body. Breaking the pill would cause too much of the drug to be released at one time. The enteric-coated pill has a special coating to protect your stomach. Breaking the pill could damage this coating. Shake the oral suspension (liquid) well just before you measure a dose. To be sure you get the correct dose, measure the liquid with a marked measuring spoon or medicine cup, not with a regular table spoon. If you do not have a dose-measuring device, ask your pharmacist for one.

If you take naproxen for a long period of time, your doctor may want to check you on a regular basis to make sure this medication is not causing harmful effects. Do not miss any scheduled visits to your doctor. Store naproxen at room temperature away from moisture and heat. The usual adult dose is 250-500 mg twice daily using regular naproxen tablets.

# DRUG DESCRIPTION

Naproxen is a member of the 2-arylpropionic acid family of NSAIDs. It is an odorless, white to off-white crystalline substance. It is lipid-soluble and practically insoluble in water. It has a melting point of 153 °C.

Naproxen is in a group of drugs called nonsteroidal anti-inflammatory drugs (NSAIDs). It works by reducing hormones that cause inflammation and pain in the body.

Naproxen is used to treat pain or inflammation caused by conditions such as arthritis, ankylosing spondylitis, tendinitis, bursitis, gout, or menstrual cramps.

Naproxen is a proprionic acid derivative related to the arylacetic acid group of nonsteroidal anti-inflammatory drugs.

The chemical names for naproxen and naproxen sodium are (S)-6-methoxy-a-methyl-2-naphthaleneacetic acid and (S)-6methoxy-a-methyl-2-naphthaleneacetic acid, sodium salt, respectively. Naproxen and naproxen sodium Naproxen has a molecular weight of 230.26 and a molecular formula of C14H14O3. Naproxen sodium has a molecular weight of 252.23 and a molecular formula of C14H13NaO3.

Note /Government Notification: These chemicals are designated as those that are used in the manufacture of the controlled substances and are important to the manufacture of the substances. For any (Control Substance) products Import and Export \*\*\* subjected to your country government laws /control substance ACT.

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The Controlled Substances Act (CSA) was enacted into law by the Congress of the United States as Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970.[1] The CSA is the federal U.S. drug policy under which the manufacture, importation, possession, use and distribution of certain substances is regulated. The Act also served as the national implementing legislation for the Single Convention on Narcotic Drugs

# This document plus the full buyer/ prescribing information, prepared for health professionals can be found at: http://www.tajapi.com or by contacting the sponsor, Taj Pharmaceuticals Limited., at: 91 022 30601000. This leaflet was prepared by

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