NAPROXEN SODIUM- naproxen sodium tablet
Direct Rx

Naproxen Sodium

Medication Guide for Nonsteroidal Anti-inflammatory Drugs (NSAIDs)
This Medication Guide has been approved by the U.S. Food and Drug Administration.

Revised: 5/2021

What is the most important information I should know about medicines called Nonsteroidal Anti-inflammatory Drugs (NSAIDs)?

NSAIDs can cause serious side effects, including:

Increased risk of a heart attack or stroke that can lead to death. This risk may happen early in treatment and may increase:

with increasing doses of NSAIDs
with longer use of NSAIDs

Do not take NSAIDs right before or after a heart surgery called a “coronary artery bypass graft (CABG)."

Avoid taking NSAIDs after a recent heart attack, unless your healthcare provider tells you to. You may have an increased risk of another heart attack if you take NSAIDs after a recent heart attack.

Increased risk of bleeding, ulcers, and tears (perforation) of the esophagus (tube leading from the mouth to the stomach), stomach and intestines:

anytime during use
without warning symptoms
that may cause death

The risk of getting an ulcer or bleeding increases with:

past history of stomach ulcers, or stomach or intestinal bleeding with use of NSAIDs
taking medicines called “corticosteroids”, “anticoagulants”, “SSRIs”, or “SNRIs”

increasing doses of NSAIDs
longer use of NSAIDs
smoking
drinking alcohol

older age
poor health
advanced liver disease
bleeding problems

NSAIDs should only be used:

exactly as prescribed
at the lowest dose possible for your treatment
for the shortest time needed

What are NSAIDs?

NSAIDs are used to treat pain and redness, swelling, and heat (inflammation) from medical conditions such as different types of arthritis, menstrual cramps, and other types of short-term pain.

Who should not take NSAIDs?

Do not take NSAIDs:

if you have had an asthma attack, hives, or other allergic reaction with aspirin or any other NSAIDs.
right before or after heart bypass surgery.

Before taking NSAIDs, tell your healthcare provider about all of your medical conditions, including if you:

have liver or kidney problems
have high blood pressure
have asthma
are pregnant or plan to become pregnant. Taking NSAIDs at about 20 weeks of pregnancy or later may harm your unborn baby. If you need to take NSAIDs for more than 2 days when you are between 20 and 30 weeks of pregnancy, your healthcare provider may need to monitor the amount of fluid in your womb around your baby. You should not take NSAIDs after about 30 weeks of pregnancy.
are breastfeeding or plan to breast feed.

Tell your healthcare provider about all of the medicines you take, including prescription or over-the-counter medicines, vitamins or herbal supplements. NSAIDs and some other medicines can interact with each other and cause serious side effects. Do not start taking any new medicine without talking to your healthcare provider first.

What are the possible side effects of NSAIDs?
NSAIDs can cause serious side effects, including:
See “What is the most important information I should know about medicines called Nonsteroidal Anti-inflammatory Drugs (NSAIDs)?”

new or worse high blood pressure
heart failure
liver problems including liver failure
kidney problems including kidney failure
low red blood cells (anemia)
life-threatening skin reactions
life-threatening allergic reactions

Other side effects of NSAIDs include: stomach pain, constipation, diarrhea, gas, heartburn, nausea, vomiting, and dizziness. Get emergency help right away if you get any of the following symptoms:

• shortness of breath or trouble breathing

• slurred speech

• chest pain

• swelling of the face or throat

• weakness in one part or side of your body

Stop taking your NSAID and call your healthcare provider right away if you get any of the following symptoms:

nausea
more tired or weaker than usual
diarrhea
itching
your skin or eyes look yellow
indigestion or stomach pain
flu-like symptoms

vomit blood
there is blood in your bowel movement or it is black and sticky like tar
unusual weight gain
skin rash or blisters with fever
swelling of the arms, legs, hands and feet

If you take too much of your NSAID, call your healthcare provider or get medical help right away.

These are not all the possible side effects of NSAIDs. For more information, ask your healthcare provider or pharmacist about NSAIDs. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

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: ScieGen Pharmaceuticals Inc, Hauppauge, NY 11788, USA

For more information, call 1-855-724-3436

Naproxen Sodium Tablets USP, 275 mg are white, capsule-shaped, film coated tablets debossed with “432” on one side and “SG” on other side.

Bottles of 30 NDC 50228-432-30
Bottles of 100 NDC 50228-432-01
Bottles of 500 NDC 50228-432-05
Bottles of 1,000 NDC 50228-432-10

Naproxen Sodium Tablets USP, 550 mg are white, capsule-shaped, film coated tablets, debossed with “433” on one side and “S & G” on either side of functional scoreline on the other side.

Bottles of 30 NDC 50228-433-30
Bottles of 100 NDC 50228-433-01
Bottles of 500 NDC 50228-433-05
Bottles of 1,000 NDC 50228-433-10

Store at 15° to 30°C (59° to 86°F) in well-closed containers.

Naproxen has been studied in patients with rheumatoid arthritis, osteoarthritis, polyarticular juvenile idiopathic arthritis, ankylosing spondylitis, tendonitis and bursitis, and acute gout. Improvement in patients treated for rheumatoid arthritis was demonstrated by a reduction in joint swelling, a reduction in duration of morning stiffness, a reduction in disease activity as assessed by both the investigator and patient, and by increased mobility as demonstrated by a reduction in walking time. Generally, response to naproxen has not been found to be dependent on age, sex, severity or duration of rheumatoid arthritis.

In patients with osteoarthritis, the therapeutic action of naproxen has been shown by a reduction in joint pain or tenderness, an increase in range of motion in knee joints, increased mobility as demonstrated by a reduction in walking time, and improvement in capacity to perform activities of daily living impaired by the disease.

In a clinical trial comparing standard formulations of naproxen 375 mg twice a day (750 mg a day) vs 750 mg twice a day (1500 mg/day), 9 patients in the 750 mg group terminated prematurely because of adverse events. Nineteen patients in the 1500 mg group terminated prematurely because of adverse events. Most of these adverse events were gastrointestinal events.

In clinical studies in patients with rheumatoid arthritis, osteoarthritis, and polyarticular juvenile idiopathic arthritis, naproxen has been shown to be comparable to aspirin and indomethacin in controlling the aforementioned measures of disease activity, but the frequency and severity of the milder gastrointestinal adverse effects (nausea, dyspepsia, heartburn) and nervous system adverse effects (tinnitus, dizziness, lightheadedness) were less in naproxen-treated patients than in those treated with aspirin or indomethacin.

In patients with ankylosing spondylitis, naproxen has been shown to decrease night pain, morning stiffness and pain at rest. In double-blind studies the drug was shown to be as effective as aspirin, but with fewer side effects.

In patients with acute gout, a favorable response to naproxen was shown by significant clearing of inflammatory changes (e.g., decrease in swelling, heat) within 24 to 48 hours, as well as by relief of pain and tenderness.

Naproxen has been studied in patients with mild to moderate pain secondary to postoperative, orthopedic, postpartum episiotomy and uterine contraction pain and dysmenorrhea. Onset of pain relief can begin within 1 hour in patients taking naproxen and within 30 minutes in patients taking naproxen sodium. Analgesic effect was shown by such measures as reduction of pain intensity scores, increase in pain relief scores, decrease in numbers of patients requiring additional analgesic medication, and delay in time to remedication. The analgesic effect has been found to last for up to 12 hours.

Naproxen may be used safely in combination with gold salts and/or corticosteroids; however, in controlled clinical trials, when added to the regimen of patients receiving corticosteroids, it did not appear to cause greater improvement over that seen with corticosteroids alone. Whether naproxen has a “steroid-sparing” effect has not been adequately studied. When added to the regimen of patients receiving gold salts, naproxen did result in greater improvement. Its use in combination with salicylates is not recommended because there is evidence that aspirin increases the rate of excretion of naproxen and data are inadequate to demonstrate that naproxen and aspirin produce greater improvement over that achieved with aspirin alone. In addition, as with other NSAIDs, the combination may result in higher frequency of adverse events than demonstrated for either product alone.

In 51Cr blood loss and gastroscopy studies with normal volunteers, daily administration of 1100 mg of naproxen sodium has been demonstrated to cause statistically significantly less gastric bleeding and erosion than 3250 mg of aspirin.

Naproxen sodium tablets, USP are nonsteroidal anti-inflammatory drugs and available as white capsule-shape tablets, containing 275 mg or 550 mg of naproxen sodium for oral administration.

Naproxen sodium is a member of the arylacetic acid group of nonsteroidal anti-inflammatory drugs. The chemical name for naproxen sodium is (S)-6-methoxy-α-methyl-2-naphthaleneacetic acid, sodium salt. Naproxen sodium has a molecular weight of 252.25 and a molecular formula of C 14H 13NaO 3. It has the following structural formula:

[Structural Formula]

Naproxen is white to creamy crystalline powder. It is soluble in water and methanol, practically insoluble in chloroform, toluene and acetone, sparingly soluble in alcohol.

Each naproxen sodium tablet, USP contains the following inactive ingredients: hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol 400, povidone, talc, and titanium dioxide.

Symptoms following acute NSAID overdosages have been typically limited to lethargy, drowsiness, nausea, vomiting, and epigastric pain, which have been generally reversible with supportive care. Gastrointestinal bleeding has occurred. Hypertension, acute renal failure, respiratory depression, and coma have occurred, but were rare [see Warnings and Precautions (5.1, 5.2)].Because naproxen sodium may be rapidly absorbed, high and early blood levels should be anticipated.

A few patients have experienced convulsions, but it is not clear whether or not these were drug-related. It is not known what dose of the drug would be life threatening. [see Warnings and Precautions (5.1, 5.2, 5.4, 5.6)].

Manage patients with symptomatic and supportive care following an NSAID overdosage. There are no specific antidotes. Consider emesis and/or activated charcoal (60 to 100 grams in adults, 1 to 2 grams per kg of body weight in pediatric patients) and/or osmotic cathartic in symptomatic patients seen within four hours of ingestion or in patients with a large overdosage (5 to 10 times the recommended dosage). Forced diuresis, alkalinization of urine, hemodialysis, or hemoperfusion may not be useful due to high protein binding.

For additional information about overdosage treatment contact a poison control center

(1-800-222-1222).

Naproxen sodium tablets are non-steroidal anti-inflammatory drugs indicated for:

the relief of the signs and symptoms of:

rheumatoid arthritis
osteoarthritis
ankylosing spondylitis
polyarticular juvenile idiopathic arthritis

Naproxen sodium tablets are also indicated for:

the relief of the signs and symptoms of:

tendonitis
bursitis
acute gout

the management of:

pain
primary dysmenorrhea

2.1 General Dosing Instructions

Carefully consider the potential benefits and risks of naproxen sodium tablets and other treatment options before deciding to use naproxen sodium tablets. Use the lowest effective dose for the shortest duration consistent with individual patient treatment goals [see WARNINGS AND PRECAUTIONS (5)].

After observing the response to initial therapy with naproxen sodium tablets, the dose and frequency should be adjusted to suit an individual patient’s needs.

Naproxen-containing products such as naproxen sodium tablets, and other naproxen products should not be used concomitantly since they all circulate in the plasma as the naproxen anion.

2.2 Rheumatoid Arthritis, Osteoarthritis and Ankylosing Spondylitis

The recommended dosages of naproxen sodium tablets are shown in Table 1.

Table 1: Recommended dosages for naproxen sodium tablets

Naproxen sodium tablets 275 mg (naproxen 250 mg with 25 mg sodium)
550 mg (naproxen 500 mg with 50 mg sodium) twice daily

During long-term administration, the dose of naproxen may be adjusted up or down depending on the clinical response of the patient. A lower daily dose may suffice for long-term administration.

The morning and evening doses do not have to be equal in size and the administration of the drug more frequently than twice daily is not necessary.

The morning and evening doses do not have to be equal in size and administration of the drug more frequently than twice daily does not generally make a difference in response.

In patients who tolerate lower doses well, the dose may be increased to naproxen 1500 mg/day for limited periods of up to 6 months when a higher level of anti-

inflammatory/analgesic activity is required. When treating such patients with naproxen 1500 mg/day, the physician should observe sufficient increased clinical benefits to offset the potential increased risk.

2.3 Polyarticular Juvenile Idiopathic Arthritis

Naproxen solid-oral dosage forms may not allow for the flexible dose titration needed in pediatric patients with polyarticular juvenile idiopathic arthritis. A liquid formulation may be more appropriate for weight-based dosing and due to the need for dose flexibility in children.

In pediatric patients, doses of 5 mg/kg/day produced plasma levels of naproxen similar to those seen in adults taking 500 mg of naproxen [see CLINICAL PHARMACOLOGY (12)]. The recommended total daily dose of naproxen is approximately 10 mg/kg given in 2 divided doses. Dosing with naproxen tablets is not appropriate for children weighing less than 50 kilograms.

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

The recommended starting dose of naproxen sodium tablets is 550 mg followed by 550 mg every 12 hours or 275 mg every 6 to 8 hours as required. The initial total daily dose should not exceed 1375 mg of naproxen sodium. Thereafter, the total daily dose should not exceed 1100 mg of naproxen sodium. Because the sodium salt of naproxen is more rapidly absorbed, naproxen sodium tablets are recommended for the management of acute painful conditions when prompt onset of pain relief is desired.

2.5 Acute Gout

Naproxen sodium tablets may also be used at a starting dose of 825 mg followed by 275 mg every 8 hours.

2.6 Non-Interchangeability with Other Formulations of Naproxen

Different dose strengths and formulations (e.g., tablets, suspension) of naproxen are not interchangeable. This difference should be taken into consideration when changing strengths or formulations.

NAPROXEN SODIUM

naproxen sodium tablet

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:72189-332(NDC:50228-433)
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
NAPROXEN SODIUM (UNII: 9TN87S3A3C) (NAPROXEN - UNII:57Y76R9ATQ)	NAPROXEN SODIUM	550 mg

Inactive Ingredients	
Ingredient Name	**Strength**
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	

Product Characteristics			
Color	white	**Score**	2 pieces
Shape	CAPSULE	**Size**	19mm
Flavor		**Imprint Code**	SG;433
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72189-332-60	60 in 1 BOTTLE; Type 0: Not a Combination Product	03/03/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA212199	03/03/2022	

Labeler - Direct Rx (079254320)

Registrant - Direct Rx (079254320)

Establishment

Name	Address	ID/FEI	Business Operations
Direct Rx		079254320	repack(72189-332)

Revised: 1/2025 Direct Rx