

Medication Guide for Non-Steroidal Anti-Inflammatory Drugs (NSAIDs)

(See the end of this Medication Guide for a list of prescription NSAID medicines.)

What is the most important information I should know about medicines call Non-Steroidal Anti-Inflammatory Drugs (NSAIDS)?

NSAID medicines may increase the chance of a heart attack or stroke that can lead to death. This chance increases:

- with longer use of NSAID medicines
- in people who have heart disease
- NSAID medicines should never be used right before or after a heart surgery called a “coronary artery bypass graft (CABG).”

NSAID medicines can cause ulcers and bleeding in the stomach and intestines at any time during treatment. Ulcers and bleeding:

- can happen without warning symptoms
- may cause death

The chance of a person getting an ulcer or bleeding increases with:

- taking medicines called “corticosteroids” and “anticoagulants”
- longer use
- smoking
- drinking alcohol
- older age
- having poor health

NSAID medicines should only be used:

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

What are Non-Steroidal Anti-Inflammatory Drugs (NSAIDs)?

NSAID medicines 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 a Non-Steroidal Anti-Inflammatory Drug (NSAID)?

Do not take an NSAID medicine:

- if you had an asthma attack, hives, or other allergic reaction with aspirin or any other NSAID medicine

- for pain right before or after heart bypass surgery

Tell your healthcare provider:

- about all of your medical conditions.
- about all of the medicines you take. NSAIDs and some other medicines can interact with each other and cause serious side effects. **Keep a list of your medicines to show to your healthcare provider and pharmacist.**
- if you are pregnant. **NSAID medicines should not be used by pregnant women late in their pregnancy.**
- if you are breastfeeding. **Talk to your doctor.**

What are the possible side effects of Non-Steroidal Anti-Inflammatory Drugs (NSAIDs)?

Serious side effects include:	Other side effects include:
<ul style="list-style-type: none">• heart attack• stroke• high blood pressure• heart failure from body swelling (fluid retention)• kidney problems including kidney failure• bleeding and ulcers in the stomach* and intestine• low red blood cells (anemia)• life-threatening skin reactions• life-threatening allergic reactions• liver problems including liver failure• asthma attacks in people who have asthma	<ul style="list-style-type: none">• stomach pain• constipation• diarrhea• gas• heartburn• nausea• vomiting• dizziness

Get emergency help right away if you have any of the following symptoms:

- shortness of breath or trouble breathing
- chest pain
- weakness in one part or side of your body
- slurred speech
- swelling of the face or throat
-

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

- nausea
- more tired or weaker than usual
- itching
- your skin or eyes look yellow
- 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 and legs, hands and feet

These are not all the side effects with NSAID medicines. Talk to your healthcare provider or pharmacist for more information about NSAID medicines.

Other information about Non-Steroidal Anti-Inflammatory Drugs (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 of these NSAID medicines 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.

NSAID medicine that need a prescription

Generic Name	Requires Prescription
Celecoxib	Celebrex
Diclofenac	Cataflam, Voltaren, Arthrotec (combined with misopristol)
Difunisal	Dolobid
Etodolac	Lodine, Lodine XL
Fenoprofen	Nalfon, Nalfon 200
Flurbiprofen	Ansaid
Ibuprofen	Motrin, Tab-Profen, Vicoprofen (combined with hydrocodone), Combunox (combined with oxycodone)
Indomethacin	Indocin, Indocin SR, Indo-Lemmon, Indomethagan
Ketoprofen	Oruvail
Ketorolac	Toradol
Mefenamic Acid	Ponstel
Meloxicam	Mobic
Nabumetone	Relafen
Naproxen	Naprosyn, Anaprox, Anaprox DS, EC-Naprosyn, Naprelan, PREVACID NapraPAC (PREVACID copackaged with NAPROSYN)
Oxaprozin	Daypro
Piroxicam	Feldene
Sulindac	Clinoril
Tolmetin	Tolectin, Tolectin DS, Tolectin 600

PREVACID[®] NapraPAC[™] (přev ě sĭd např ě pak)
(lansoprazole delayed release capsules and naproxen tablets kit)

WHAT IS PREVACID[®] NAPRAPAC[™]?

PREVACID NapraPAC contains two medicines:

1. PREVACID[®] (lansoprazole) Delayed-Release Capsules. PREVACID is a proton pump inhibitor (a medicine that reduces stomach acid); and
2. NAPROSYN[®] (naproxen) Tablets. NAPROSYN is a nonsteroidal anti-inflammatory drug (NSAID). Please read the above information regarding the benefits and risks of NSAIDs, including NAPROSYN.

PREVACID NapraPAC is used to lower the chance of getting another stomach ulcer in adult patients who have had stomach ulcers and who need to take an NSAID to treat the signs and symptoms of rheumatoid arthritis, osteoarthritis, and/or ankylosing spondylitis.

It is not known if PREVACID NapraPAC lowers the risk of ulcers of the intestines or if PREVACID NapraPAC reduces the risk of bleeding from stomach ulcers and ulcers of the intestines.

PREVACID NapraPAC comes in three dose strengths:

1. One PREVACID 15 mg capsule and two NAPROSYN 250 mg tablets
2. One PREVACID 15 mg capsule and two NAPROSYN 375 mg tablets
3. One PREVACID 15 mg capsule and two NAPROSYN 500 mg tablets

The lowest possible dose for the shortest time possible should be prescribed to treat your condition.

PREVACID NapraPAC has not been studied in children.

Can I take other medicines with PREVACID NapraPAC?

Tell your doctor about all of the medicines you take including prescription and nonprescription medicines, vitamins, and herbal supplements. Both of the medicines in PREVACID NapraPAC can affect other medicines you take and sometimes cause serious side effects. Especially, tell your doctor if you take:

- blood pressure medicines
- aspirin
- water pills (diuretics)
- lithium
- methotrexate
- warfarin (Coumadin)
- theophylline
- sucralfate

- ketoconazole
- ampicillin
- iron salts
- digoxin

How should I take PREVACID NapraPAC?

- **In the morning before eating**, take one PREVACID capsule and one NAPROSYN tablet with a glass of water. **In the evening**, take the second NAPROSYN tablet with a glass of water.
- Swallow PREVACID capsules whole. Do not crush or chew PREVACID capsules. If you take sucralfate, PREVACID should be taken 30 minutes before sucralfate.

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