



Oral Suspension USP



HIGHLIGHTS OF PRESCRIBING INFORMATION

WARNING: RISK OF SERIOUS CARDIOVASCULAR AND GASTROINTESTINAL EVENTS
• **Nonsteroidal anti-inflammatory drug (NSAID)** cases an increased risk of serious cardiovascular thrombotic events, including myocardial infarction and stroke, which can be fatal. This risk may occur any time during use and may increase with duration of use.

NSAIDs cause an increased risk of serious gastrointestinal (GI) adverse events including bleeding, ulceration, and perforation of the stomach or intestine, which can be fatal. These events can occur at any time during use and without warning symptoms. Elderly patients and patients with a prior history of peptic ulcer disease and/or bleeding are at greater risk for serious GI events.

INDICATIONS AND USAGE

Naproxen oral suspension is a nonsteroidal anti-inflammatory drug indicated for the relief of the signs and symptoms of:

- rheumatoid arthritis
- osteoarthritis
- ankylosing spondylitis
- polyarthralgia/polyarthropathic arthritis
- bursitis
- sciatica
- the management of:
- pain
- primary dysmenorrhea

CONTRAINDICATIONS

Known hypersensitivity to naproxen or any components of this product (2)
• History of asthma, urticaria, or other allergic-type reactions after taking aspirin or other NSAIDs (4)
• In the setting of CABG surgery (5)

WARNINGS AND PRECAUTIONS

5.1 Cardiovascular Thrombotic Events
NSAIDs, including naproxen, cause serious thrombotic events including myocardial infarction, stroke, and other adverse cardiovascular events. These events can occur at any time during use and without warning symptoms. Elderly patients and patients with a prior history of peptic ulcer disease and/or bleeding are at greater risk for serious GI events.

5.2 Gastrointestinal Bleeding, Ulceration, and Perforation

NSAIDs cause an increased risk of serious gastrointestinal (GI) adverse events including bleeding, ulceration, and perforation of the stomach or intestine, which can be fatal. These events can occur at any time during use and without warning symptoms. Elderly patients and patients with a prior history of peptic ulcer disease and/or bleeding are at greater risk for serious GI events.

5.3 Hematologic Toxicity

NSAIDs may cause a decrease in hemoglobin and hematocrit. In some patients, this decrease may be associated with occult bleeding or other causes of iron deficiency.

5.4 Renal Toxicity and Hypotension

NSAIDs may cause renal toxicity, including acute renal failure, which can be fatal. These events can occur at any time during use and without warning symptoms. Elderly patients and patients with a prior history of peptic ulcer disease and/or bleeding are at greater risk for serious GI events.

5.5 Hepatic Toxicity

NSAIDs may cause liver toxicity, including acute liver failure, which can be fatal. These events can occur at any time during use and without warning symptoms. Elderly patients and patients with a prior history of peptic ulcer disease and/or bleeding are at greater risk for serious GI events.

5.6 Anaphylactic Reactions

NSAIDs may cause anaphylactic reactions, which can be fatal. These events can occur at any time during use and without warning symptoms. Elderly patients and patients with a prior history of peptic ulcer disease and/or bleeding are at greater risk for serious GI events.

5.7 Discontinuation of NSAID Therapy

NSAIDs may cause a rebound effect, including a flare-up of symptoms, when therapy is discontinued. This effect is more likely to occur in patients with a longer duration of therapy.

5.8 Pregnancy, Labor, and Delivery

NSAIDs may cause fetal or infant harm, including bleeding, when used during pregnancy, labor, or delivery. NSAIDs should be avoided during the third trimester of pregnancy.

5.9 Breastfeeding

NSAIDs are excreted in breast milk. Caution should be exercised when NSAIDs are administered to a nursing woman.

ADVERSE REACTIONS

Most common adverse reactions to naproxen were dyspepsia, abdominal pain, nausea, headache, rash, asthenia, and dizziness (1).
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5.10 Drug Interactions

NSAIDs may interact with other drugs, including anticoagulants, antiplatelet drugs, and other NSAIDs. Caution should be exercised when NSAIDs are administered to patients taking these drugs.

5.11 Laboratory Tests

NSAIDs may interfere with laboratory tests, including hemoglobin and hematocrit. Patients should be monitored for these effects.

5.12 Description of Naproxen Oral Suspension

Naproxen oral suspension is a white to off-white suspension. The concentration is 250 mg/5 mL. It contains 10% alcohol.

5.13 How to Use Naproxen Oral Suspension

Shake the suspension well before use. Measure the dose carefully. Do not use the suspension if it has changed in color or consistency.

5.14 Storage and Stability

Store the suspension at controlled room temperature (20° to 25°C). Do not freeze. Discard any remaining suspension after 30 days.

5.15 Patient Counseling Information

Patients should be informed of the risks and benefits of NSAIDs. They should be advised to take the suspension as directed and to avoid alcohol.

5.16 Clinical Trials

NSAIDs have been shown to be effective in the treatment of pain and inflammation in clinical trials. The most common adverse reactions were dyspepsia and headache.

5.17 Reference

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Medication Guide for Nonsteroidal Anti-inflammatory Drugs (NSAIDs)

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 "NNHIs"
- increasing doses of NSAIDs
- older age
- longer use of NSAIDs
- poor health
- smoking
- advanced liver disease
- drinking alcohol

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, 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.

How should I take naproxen oral suspension?
Use ONLY a calibrated measuring device to measure your dose of naproxen oral suspension. DO NOT use a household teaspoon or tablespoon. Your pharmacist can provide you with the proper device to correctly measure your dose.

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:

- new or worse high blood pressure
- liver problems including liver failure
- kidney problems including kidney failure
- low red blood cells (anemia)
- life-threatening allergic 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
- nausea
- vomit blood
- more tired or weaker than usual
- there is blood in your bowel movement or it is black and sticky like tar
- diarrhea
- unusual weight gain
- itching
- skin rash or blisters with fever
- your skin or eyes look yellow
- 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.

Leaflet Size: 350 x 580 mm
Prefold: 35x35 mm
Colors: BLACK
40 GSM Bible Paper



