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Naproxen: Patient drug information

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(For additional information see "Naproxen: Drug information" and see "Naproxen: Pediatric drug information")

Brand Names: US

Aleve [OTC]; All Day Pain Relief [OTC]; All Day Relief [OTC]; Anaprox DS [DSC]; EC-Naprosyn; EC-Naproxen; Flanax Pain Relief [DSC]; Flanax Pain Relief [OTC] [DSC]; GoodSense Naproxen Sodium [OTC]; Mediproxen [OTC]; Naprelan; Naprosyn; Naproxen Comfort Pac [DSC]

Brand Names: Canada

Anaprox; Anaprox DS; APO-Napro-Na; APO-Naproxen; APO-Naproxen EC; APO-Naproxen SR; MYLAN-Naproxen EC [DSC]; MYLAN-Naproxen [DSC]; Naprosyn; Naproxen-Na; Naxen EC; Pediapharm Naproxen; PMS-Naproxen EC; PMS-Naproxen [DSC]; PRO-Naproxen EC; TEVA-Naproxen; TEVA-Naproxen EC; TEVA-Naproxen Sodium; TEVA-Naproxen Sodium DS

Warning

- This drug may raise the risk of heart and blood vessel problems like heart attack and stroke. These effects can be deadly. The risk may be greater if you have heart disease or risks for heart disease. However, it can also be raised even if you do not have heart disease or risks for heart disease. The risk can happen within the first weeks of using this drug and may be greater with higher doses or long-term use. Do not use this drug right before or after bypass heart surgery.
- This drug may raise the chance of severe and sometimes deadly stomach or bowel problems like ulcers or bleeding. The risk is greater in older people, and in people who

have had stomach or bowel ulcers or bleeding before. These problems may occur without warning signs.

What is this drug used for?

- It is used to ease pain, swelling, and fever.
- It is used to ease painful period (menstrual) cycles.
- It is used to treat some types of arthritis.
- It is used to treat ankylosing spondylitis.
- It is used to treat gout attacks.
- It may be given to you for other reasons. Talk with the doctor.

What do I need to tell my doctor BEFORE I take this drug?

- If you are allergic to this drug; any part of this drug; or any other drugs, foods, or substances. Tell your doctor about the allergy and what signs you had.
- If you have an allergy to aspirin or nonsteroidal anti-inflammatory drugs (NSAIDs) like ibuprofen or naproxen.
- If you have ever had asthma caused by a salicylate drug like aspirin or a drug like this one like NSAIDs.
- If you have any of these health problems: GI (gastrointestinal) bleeding or kidney problems.
- If you have any of these health problems: Heart failure (weak heart) or a recent heart attack.
- If you are taking any other NSAID, a salicylate drug like aspirin, or pemetrexed.
- If you are having trouble getting pregnant or you are having your fertility checked.
- If you are pregnant or may be pregnant. Avoid taking this drug at 20 weeks or later in pregnancy unless your doctor tells you otherwise. Do not take this drug if you are more than 30 weeks pregnant.
 - This is not a list of all drugs or health problems that interact with this drug.
 - Tell your doctor and pharmacist about all of your drugs (prescription or OTC, natural products, vitamins) and health problems. You must check to make sure that it is safe for you to take this drug with all of your drugs and health problems. Do not start, stop, or change the dose of any drug without checking with your doctor.

What are some things I need to know or do while I take this drug?

- Tell all of your health care providers that you take this drug. This includes your doctors, nurses, pharmacists, and dentists.
- Have your blood work checked if you are on this drug for a long time. Talk with your doctor.
- This drug may affect certain lab tests. Tell all of your health care providers and lab workers that you take this drug.
- High blood pressure has happened with drugs like this one. Have your blood pressure checked as you have been told by your doctor.
- Talk with your doctor before you drink alcohol.
- If you smoke, talk with your doctor.
- Do not take more than what your doctor told you to take. Taking more than you are told may raise your chance of very bad side effects.
- Do not take this drug for longer than you were told by your doctor.
- If you have asthma, talk with your doctor. You may be more sensitive to this drug.
- You may bleed more easily. Be careful and avoid injury. Use a soft toothbrush and an electric razor.
- The chance of heart failure is raised with the use of drugs like this one. In people who already have heart failure, the chance of heart attack, having to go to the hospital for heart failure, and death is raised. Talk with the doctor.
- The chance of heart attack and heart-related death is raised in people taking drugs like this one after a recent heart attack. People taking drugs like this one after a first heart attack were also more likely to die in the year after the heart attack compared with people not taking drugs like this one. Talk with the doctor.
- If you are taking aspirin to help prevent a heart attack, talk with your doctor.
- If you are on a low-sodium or sodium-free diet, talk with your doctor. Some of these products have sodium.
- Liver problems have happened with drugs like this one. Sometimes, this has been deadly. Call your doctor right away if you have signs of liver problems like dark urine, feeling tired, not hungry, upset stomach or stomach pain, light-colored stools, throwing up, or yellow skin or eyes.
- A severe and sometimes deadly reaction has happened with drugs like this one. Most of the time, this reaction has signs like fever, rash, or swollen glands with problems in body

organs like the liver, kidney, blood, heart, muscles and joints, or lungs. If you have questions, talk with the doctor.

- If you are 60 or older, use this drug with care. You could have more side effects.
- NSAIDs like this drug may affect egg release (ovulation) in women. This may cause you to not be able to get pregnant. This goes back to normal when this drug is stopped. Talk with your doctor.
- This drug may cause harm to the unborn baby if you take it while you are pregnant. If you are pregnant or you get pregnant while taking this drug, call your doctor right away.
- Tell your doctor if you are breast-feeding. You will need to talk about any risks to your baby.

What are some side effects that I need to call my doctor about right away?

WARNING/CAUTION: Even though it may be rare, some people may have very bad and sometimes deadly side effects when taking a drug. Tell your doctor or get medical help right away if you have any of the following signs or symptoms that may be related to a very bad side effect:

- Signs of an allergic reaction, like rash; hives; itching; red, swollen, blistered, or peeling skin with or without fever; wheezing; tightness in the chest or throat; trouble breathing, swallowing, or talking; unusual hoarseness; or swelling of the mouth, face, lips, tongue, or throat.
- Signs of bleeding like throwing up or coughing up blood; vomit that looks like coffee grounds; blood in the urine; black, red, or tarry stools; bleeding from the gums; abnormal vaginal bleeding; bruises without a cause or that get bigger; or bleeding you cannot stop.
- Signs of kidney problems like unable to pass urine, change in how much urine is passed, blood in the urine, or a big weight gain.
- Signs of high potassium levels like a heartbeat that does not feel normal; feeling confused; feeling weak, lightheaded, or dizzy; feeling like passing out; numbness or tingling; or shortness of breath.
- Signs of high blood pressure like very bad headache or dizziness, passing out, or change in eyesight.
- Shortness of breath, a big weight gain, or swelling in the arms or legs.
- Chest pain or pressure or a fast heartbeat.
- Weakness on 1 side of the body, trouble speaking or thinking, change in balance, drooping on one side of the face, or blurred eyesight.

- Feeling very tired or weak.
- · Ringing in ears.
- Very bad back pain.
- Flu-like signs.
- · Swollen gland.
- A severe skin reaction (Stevens-Johnson syndrome/toxic epidermal necrolysis) may happen. It can cause severe health problems that may not go away, and sometimes death. Get medical help right away if you have signs like red, swollen, blistered, or peeling skin (with or without fever); red or irritated eyes; or sores in your mouth, throat, nose, or eyes.

What are some other side effects of this drug?

All drugs may cause side effects. However, many people have no side effects or only have minor side effects. Call your doctor or get medical help if any of these side effects or any other side effects bother you or do not go away:

- Stomach pain or heartburn.
- Upset stomach.
- Constipation.
- · Dizziness or headache.
- Feeling sleepy.

These are not all of the side effects that may occur. If you have questions about side effects, call your doctor. Call your doctor for medical advice about side effects.

You may report side effects to your national health agency.

How is this drug best taken?

Use this drug as ordered by your doctor. Read all information given to you. Follow all instructions closely.

All products:

- Take with or without food. Take with food if it causes an upset stomach.
- Take with a full glass of water.
- Do not take sucralfate or antacids that have magnesium or aluminum with this drug.

Modified-release tablets:

• Swallow whole. Do not chew, break, or crush.

Suspension:

- Shake well before use.
- Measure liquid doses carefully. Use the measuring device that comes with this drug. If there is none, ask the pharmacist for a device to measure this drug.
- Do not use a household teaspoon or tablespoon to measure this drug. Doing so could lead to the dose being too high.

What do I do if I miss a dose?

- If you take this drug on a regular basis, take a missed dose as soon as you think about it.
- If it is close to the time for your next dose, skip the missed dose and go back to your normal time.
- Do not take 2 doses at the same time or extra doses.
- Many times this drug is taken on an as needed basis. Do not take more often than told by the doctor.

How do I store and/or throw out this drug?

- Store at room temperature protected from light. Store in a dry place. Do not store in a bathroom.
- Keep all drugs in a safe place. Keep all drugs out of the reach of children and pets.
- Throw away unused or expired drugs. Do not flush down a toilet or pour down a drain unless you are told to do so. Check with your pharmacist if you have questions about the best way to throw out drugs. There may be drug take-back programs in your area.

General drug facts

- If your symptoms or health problems do not get better or if they become worse, call your doctor.
- Do not share your drugs with others and do not take anyone else's drugs.
- Some drugs may have another patient information leaflet. If you have any questions about this drug, please talk with your doctor, nurse, pharmacist, or other health care provider.

• If you think there has been an overdose, call your poison control center or get medical care right away. Be ready to tell or show what was taken, how much, and when it happened.

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Topic 11801 Version 264.0