

**REVIEWED**

By tigre at 1:25 pm, Nov 17, 2015

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Naproxen

pronounced as (na prox' en)

Notice:

[Posted 07/09/2015]

AUDIENCE: Health Professional, Consumer

ISSUE: FDA is strengthening an existing label warning that non-aspirin nonsteroidal anti-inflammatory drugs (NSAIDs) increase the chance of a heart attack or stroke. Based on FDA's comprehensive review of new safety information, FDA is requiring updates to the drug labels of all prescription NSAIDs. As is the case with current prescription NSAID labels, the Drug Facts labels of over-the-counter (OTC) non-aspirin NSAIDs already contain information on heart attack and stroke risk. FDA will also request updates to the OTC non-aspirin NSAID Drug Facts labels. See the FDA Drug Safety Communication (Table 1) at: <http://www.fda.gov/Drugs/DrugSafety/ucm451800.htm> [<http://www.fda.gov/Drugs/DrugSafety/ucm451800.htm>] for a list of non-aspirin nonsteroidal anti-inflammatory drug products.

Prescription NSAID labels will be revised to reflect the following information:

1. The risk of heart attack or stroke can occur as early as the first weeks of using an NSAID. The risk may increase with longer use of the NSAID.
2. The risk appears greater at higher doses.
3. It was previously thought that all NSAIDs may have a similar risk. Newer information makes it less clear that the risk for heart attack or stroke is similar for all NSAIDs; however, this newer information is not sufficient for us to determine that the risk of any particular NSAID is definitely higher or lower than that of any other particular NSAID.
4. NSAIDs can increase the risk of heart attack or stroke in patients with or without heart disease or risk factors for heart disease. A large number of studies support this finding, with varying estimates of how much the risk is increased, depending on the drugs and the doses studied.

5. In general, patients with heart disease or risk factors for it have a greater likelihood of heart attack or stroke following NSAID use than patients without these risk factors because they have a higher risk at baseline.
6. Patients treated with NSAIDs following a first heart attack were more likely to die in the first year after the heart attack compared to patients who were not treated with NSAIDs after their first heart attack.
7. There is an increased risk of heart failure with NSAID use.

BACKGROUND: The risk of heart attack and stroke with NSAIDs, either of which can lead to death, was first described in 2005 in the Boxed Warning and Warnings and Precautions sections of the prescription drug labels. Since then, FDA reviewed a variety of new safety information on prescription and OTC NSAIDs, including observational studies, a large combined analysis of clinical trials, and other scientific publications. These studies were also discussed at a joint meeting of the Arthritis Advisory Committee and Drug Safety and Risk Management Advisory Committee held on February 10-11, 2014.

RECOMMENDATION: Patients and health care professionals should remain alert for heart-related side effects the entire time that NSAIDs are being taken. Patients taking NSAIDs should seek medical attention immediately if they experience symptoms such as chest pain, shortness of breath or trouble breathing, weakness in one part or side of their body, or slurred speech.

For more information visit the FDA website at: <http://www.fda.gov/Safety/MedWatch/SafetyInformation> [<http://www.fda.gov/Safety/MedWatch/SafetyInformation>] and <http://www.fda.gov/Drugs/DrugSafety> [<http://www.fda.gov/Drugs/DrugSafety>] .

IMPORTANT WARNING:

People who take nonsteroidal anti-inflammatory drugs (NSAIDs) (other than aspirin) such as naproxen may have a higher risk of having a heart attack or a stroke than people who do not take these medications. These events may happen without warning and may cause death. This risk may be higher for people who take NSAIDs for a long time. Tell your doctor if you or anyone in your family has or has ever had heart disease, a heart attack, or a stroke, if you smoke, and if you have or have ever had high cholesterol, high blood pressure, or diabetes. Get emergency medical help right away if you experience any of the following symptoms: chest pain, shortness of breath, weakness in one part or side of the body, or slurred speech.

If you will be undergoing a coronary artery bypass graft (CABG; a type of heart surgery), you should not take naproxen right before or right after the surgery.

NSAIDs such as naproxen may cause ulcers, bleeding, or holes in the stomach or intestine. These

problems may develop at any time during treatment, may happen without warning symptoms, and may cause death. The risk may be higher for people who take NSAIDs for a long time, are older in age, have poor health, or who drink three or more alcoholic drinks per day while taking naproxen. Tell your doctor if you take any of the following medications: anticoagulants ("blood thinners") such as warfarin (Coumadin); aspirin; other NSAIDs such as ibuprofen (Advil, Motrin) and ketoprofen (Orudis KT, Actron); or oral steroids such as dexamethasone (Decadron, Dexone), methylprednisolone (Medrol), and prednisone (Deltasone). Also tell your doctor if you have or have ever had ulcers, bleeding in your stomach or intestines, or other bleeding disorders. If you experience any of the following symptoms, stop taking naproxen and call your doctor: stomach pain, heartburn, vomit that is bloody or looks like coffee grounds, blood in the stool, or black and tarry stools.

Keep all appointments with your doctor and the laboratory. Your doctor will monitor your symptoms carefully and will probably order certain tests to check your body's response to naproxen. Be sure to tell your doctor how you are feeling so that your doctor can prescribe the right amount of medication to treat your condition with the lowest risk of serious side effects.

Your doctor or pharmacist will give you the manufacturer's patient information sheet (Medication Guide) when you begin treatment with prescription naproxen and each time you refill your prescription. Read the information carefully and ask your doctor or pharmacist if you have any questions. You can also visit the Food and Drug Administration (FDA) website (<http://www.fda.gov/Drugs/DrugSafety/ucm085729.htm> [<http://www.fda.gov/Drugs/DrugSafety/ucm085729.htm>]) or the manufacturer's website to obtain the Medication Guide.

Why is this medication prescribed?

Prescription naproxen is used to relieve pain, tenderness, swelling, and stiffness caused by osteoarthritis (arthritis caused by a breakdown of the lining of the joints), rheumatoid arthritis (arthritis caused by swelling of the lining of the joints), juvenile arthritis (a form of joint disease in children), and ankylosing spondylitis (arthritis that mainly affects the spine). Prescription naproxen tablets, extended-release tablets, and suspension are also used to relieve shoulder pain caused by bursitis (inflammation of a fluid-filled sac in the shoulder joint), tendinitis (inflammation of the tissue that connects muscle to bone), gouty arthritis (attacks of joint pain caused by a build-up of certain substances in the joints), and pain from other causes, including menstrual pain (pain that happens before or during a menstrual period). Nonprescription naproxen is used to reduce fever and to relieve mild pain from headaches, muscle aches, arthritis, menstrual periods, the common cold, toothaches, and backaches. Naproxen is in a class of medications called NSAIDs. It works by stopping the body's production of a substance that causes pain, fever, and inflammation.

How should this medicine be used?

Prescription naproxen comes as a regular tablet, delayed-release (a tablet that releases the medication in the intestine to prevent damage to the stomach) tablet, an extended-release (long-acting) tablet, and a suspension (liquid) to take by mouth. The extended-release tablets are usually taken once a day. The tablets, delayed-release tablets, and suspension are usually taken twice a day for arthritis. The tablets and suspension are usually taken every 8 hours for gout, and every 6 to 8 hours as needed for pain. If you are taking naproxen on a regular basis, you should take it at the same time(s) every day.

Nonprescription naproxen comes as tablet and a gelatin coated tablet to take by mouth. It is usually taken with a full glass of water every 8 to 12 hours as needed. Nonprescription naproxen may be taken with food or milk to prevent nausea.

Follow the directions on the package or prescription label carefully, and ask your doctor or pharmacist to explain any part you do not understand. Take naproxen exactly as directed. Do not take more or less of it or take it more often than prescribed by your doctor or written on the package.

Shake the liquid well before each use to mix the medication evenly. Use the measuring cup provided to measure each dose of the liquid.

Swallow the delayed-release tablets and extended release tablets whole; do not split, chew, or crush them.

If you are taking naproxen to relieve the symptoms of arthritis, your symptoms may begin to improve within 1 week. It may take 2 weeks or longer for you to feel the full benefit of the medication.

Stop taking nonprescription naproxen and call your doctor if your symptoms get worse, you develop new or unexpected symptoms, the part of your body that was painful becomes red or swollen, your pain lasts for more than 10 days, or your fever lasts for more than 3 days.

Other uses for this medicine

Naproxen is also sometimes used to treat Paget's disease of bone (a condition in which the bones become abnormally thick, fragile, and misshapen) and Bartter syndrome (a condition in which the body does not absorb enough potassium, causing muscle cramping and weakness and other symptoms). Talk to your doctor about the risks of using this medication for your condition.

This medication is sometimes prescribed for other uses; ask your doctor or pharmacist for more information.

What special precautions should I follow?

Before taking naproxen,

- tell your doctor and pharmacist if you are allergic to naproxen, aspirin or other NSAIDs such as

ibuprofen (Advil, Motrin) and ketoprofen (Orudis KT, Actron), any medications for pain or fever, or any other medications.

- tell your doctor and pharmacist what prescription and nonprescription medications, vitamins, nutritional supplements, and herbal products you are taking or plan to take. Be sure to mention the medications listed in the IMPORTANT WARNING section and any of the following: angiotensin-converting enzyme (ACE) inhibitors such as benazepril (Lotensin), captopril (Capoten), enalapril (Vasotec), fosinopril (Monopril), lisinopril (Prinivil, Zestril), moexipril (Univasc), perindopril (Aceon), quinapril (Accupril), ramipril (Altace), and trandolapril (Mavik); angiotensin II receptor antagonists (angiotensin receptor blockers; ARBs) such as candesartan (Atacand), eprosartan (Teveten), irbesartan (Avapro, in Avalide), losartan (Cozaar, in Hyzaar), olmesartan (Benicar), telmisartan (Micardis), and valsartan (Diovan); beta blockers such as atenolol (Tenormin), labetalol (Normodyne), metoprolol (Lopressor, Toprol XL), nadolol (Corgard), and propranolol (Inderal); cholestyramine (Questran); diuretics ('water pills'); lithium (Eskalith, Lithobid), medications for diabetes; methotrexate (Rheumatrex); probenecid (Benemid); selective serotonin reuptake inhibitors such as citalopram (Celexa), escitalopram (Lexapro), fluoxetine (Prozac), fluvoxamine (Luvox), paroxetine (Paxil), and sertraline (Zoloft); sulfa medications such as sulfamethoxazole (in Septra, Bactrim); and warfarin (Coumadin). If you are taking the delayed-release tablets, also tell your doctor if you are taking antacids or sucralfate (Carafate). Your doctor may need to change the doses of your medication or monitor you more carefully for side effects.
- do not take nonprescription naproxen with any other medication for pain unless your doctor tells you that you should.
- tell your doctor if you have been told to follow a low sodium diet and if you have or have ever had any of the conditions mentioned in the IMPORTANT WARNING section or asthma, especially if you also have frequent stuffed or runny nose or nasal polyps (swelling of the inside of the nose); swelling of the hands, arms, feet, ankles, or lower legs; anemia (red blood cells do not bring enough oxygen to all parts of the body); or liver or kidney disease.
- tell your doctor if you are pregnant, especially if you are in the last few months of your pregnancy, you plan to become pregnant, or you are breast-feeding. If you become pregnant while taking naproxen, call your doctor.
- talk to your doctor about the risks and benefits of taking naproxen if you are 65 years of age or older. Older adults should usually take lower doses of naproxen for short periods of time because higher doses used regularly may not be more effective and are more likely to cause serious side effects.
- if you are having surgery, including dental surgery, tell the doctor or dentist that you are taking naproxen.
- you should know that this medication may make you dizzy, drowsy, or depressed. Do not drive a car or operate machinery until you know how this drug affects you.
- remember that alcohol can add to the drowsiness caused by this medication.

What special dietary instructions should I follow?

Unless your doctor tells you otherwise, continue your normal diet.

What should I do if I forget a dose?

Take the missed dose as soon as you remember it. However, if it is almost time for the next dose, skip the missed dose and continue your regular dosing schedule. Do not take a double dose to make up for a missed one.

What side effects can this medication cause?

Naproxen may cause side effects. Tell your doctor if any of these symptoms are severe or do not go away:

- constipation
- diarrhea
- gas
- excessive thirst
- headache
- dizziness
- lightheadedness
- drowsiness
- difficulty falling asleep or staying asleep
- burning or tingling in the arms or legs
- cold symptoms
- ringing in the ears
- hearing problems

Some side effects can be serious. If you experience any of the following symptoms, or those mentioned in the IMPORTANT WARNING section, call your doctor immediately. Do not take any more naproxen until you speak to your doctor:

- changes in vision
- feeling that the tablet is stuck in your throat
- unexplained weight gain
- sore throat, fever, chills, and other signs of infection
- blisters
- rash
- skin reddening

- itching
- hives
- swelling of the eyes, face, lips, tongue, throat, arms, hands, feet, ankles, or lower legs
- difficulty breathing or swallowing
- hoarseness
- excessive tiredness
- pain in the upper right part of the stomach
- nausea
- yellowing of the skin or eyes
- flu-like symptoms
- bruises or purple blotches under the skin
- fast heartbeat
- cloudy, discolored, or bloody urine
- back pain
- difficult or painful urination
- decreased urination
- loss of appetite
- confusion

Naproxen may cause other side effects. Call your doctor if you have any unusual problems while taking this medication.

If you experience a serious side effect, you or your doctor may send a report to the Food and Drug Administration's (FDA) MedWatch Adverse Event Reporting program online (<http://www.fda.gov/Safety/MedWatch> [<http://www.fda.gov/Safety/MedWatch>]) or by phone (1-800-332-1088).

What should I know about storage and disposal of this medication?

Keep this medication in the container it came in, tightly closed, and out of reach of children. Store it at room temperature and away from excess heat and moisture (not in the bathroom). Throw away any medication that is outdated or no longer needed. Talk to your pharmacist about the proper disposal of your medication.

In case of emergency/overdose

In case of overdose, call your local poison control center at 1-800-222-1222. If the victim has collapsed or is not breathing, call local emergency services at 911.

Symptoms of overdose may include the following:

- dizziness
- extreme tiredness
- drowsiness
- stomach pain
- heartburn
- nausea
- vomiting
- slow or difficult breathing

What other information should I know?

Before having any laboratory test, tell your doctor and the laboratory personnel that you are taking naproxen.

If you are taking prescription naproxen, do not let anyone else take your medication. Ask your pharmacist any questions you have about refilling your prescription.

It is important for you to keep a written list of all of the prescription and nonprescription (over-the-counter) medicines you are taking, as well as any products such as vitamins, minerals, or other dietary supplements. You should bring this list with you each time you visit a doctor or if you are admitted to a hospital. It is also important information to carry with you in case of emergencies.

Brand names

- Aleve ®
- Anaprox ®
- Anaprox ® DS

- EC-Naprosyn ®
- Flanax ®
- Naprelan ®

- Naprosyn ®

Brand names of combination products

- Aleve PM ® (containing Diphenhydramine, Naproxen)
- Treximet ® (containing Naproxen, Sumatriptan)

- Vimovo ® (containing Esomeprazole, Naproxen)

Last Revised - 09/15/2015



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Page last updated: 19 October 2015