

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

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APPROVED LABELING



9183908

**Patient Information about
VIOXX® (rofecoxib tablets and oral suspension)
VIOXX® (pronounced "VI-ox")
for Osteoarthritis, Rheumatoid Arthritis and Pain
Generic name: rofecoxib ("ro-fa-COX-ib")**

You should read this information before you start taking VIOXX*. Also, read the leaflet each time you refill your prescription, in case any information has changed. This leaflet provides only a summary of certain information about VIOXX. Your doctor or pharmacist can give you an additional leaflet that is written for health professionals that contains more complete information. This leaflet does not take the place of careful discussions with your doctor. You and your doctor should discuss VIOXX when you start taking your medicine and at regular checkups.

What is VIOXX?

VIOXX is a nonsteroidal anti-inflammatory drug (NSAID) that is used to reduce pain and inflammation (swelling and soreness). VIOXX is available as a tablet or a liquid that you take by mouth.

VIOXX is a medicine for:

- relief of osteoarthritis (the arthritis caused by age-related "wear and tear" on bones and joints)
- relief of rheumatoid arthritis in adults
- management of acute pain in adults (like the short-term pain you can get after a dental or surgical operation)
- treatment of menstrual pain (pain during women's monthly periods).

Who should not take VIOXX?

Do not take VIOXX if you:

- have had an allergic reaction such as asthma attacks, hives, or swelling of the throat and face to aspirin or other NSAIDs (for example, ibuprofen and naproxen).
- have had an allergic reaction to rofecoxib, which is the active ingredient of VIOXX, or to any of its inactive ingredients. (See Inactive Ingredients at the end of this leaflet.)

What should I tell my doctor before and during treatment with VIOXX?

Tell your doctor if you are:

- pregnant or plan to become pregnant. VIOXX should not be used in late pregnancy because it may harm the fetus.
- breast-feeding or plan to breast-feed. It is not known whether VIOXX is passed through to human breast milk and what its effects could be on a nursing child.

Tell your doctor if you have:

- history of angina, heart attack or a blocked artery in your heart

- kidney disease
- liver disease
- heart failure
- high blood pressure
- had an allergic reaction to aspirin or other NSAIDs
- had a serious stomach problem in the past.

Tell your doctor about:

- any other medical problems or allergies you have now or have had.
- all medicines that you are taking or plan to take, even those you can get without a prescription.

Tell your doctor if you develop:

- serious stomach problems such as ulcer or bleeding symptoms (for instance, stomach burning or black stools, which are signs of possible stomach bleeding).
- unexplained weight gain or swelling of the feet and/or legs.
- skin rash or allergic reactions. If you have a severe allergic reaction, get medical help right away.

How should I take VIOXX?

VIOXX should be taken once a day. Your doctor will decide what dose of VIOXX you should take and how long you should take it. You may take VIOXX with or without food.

Can I take VIOXX with other medicines?

Tell your doctor about all of the other medicines you are taking or plan to take while you are on VIOXX, even other medicines that you can get without a prescription. Your doctor may want to check that your medicines are working properly together if you are taking other medicines such as:

- warfarin (a blood thinner)
- theophylline (a medicine used to treat asthma)
- rifampin (an antibiotic)
- ACE inhibitors (medicines used for high blood pressure and heart failure)
- lithium (a medicine used to treat a certain type of depression).

VIOXX cannot take the place of aspirin for prevention of heart attack or stroke. If you are currently taking aspirin for this purpose, you should not discontinue taking aspirin without consulting your doctor.

What are the possible side effects of VIOXX?

Serious but rare side effects that have been reported in patients taking VIOXX and/or related medicines have included:

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8063816
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VIOXX®



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and oral suspension)
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- Serious stomach problems, such as stomach and intestinal bleeding, can occur with or without warning symptoms. These problems, if severe, could lead to hospitalization or death. Although this happens rarely, you should watch for signs that you may have this serious side effect and tell your doctor right away.
- Heart attacks and similar serious events have been reported in patients taking VIOXX.
- Serious allergic reactions including swelling of the face, lips, tongue, and/or throat which may cause difficulty breathing or swallowing and wheezing occur rarely but may require treatment right away. Severe skin reactions have also been reported.
- Serious kidney problems occur rarely, including acute kidney failure and worsening of chronic kidney failure.
- Severe liver problems, including hepatitis, jaundice and liver failure, occur rarely in patients taking NSAIDs, including VIOXX. Tell your doctor if you develop symptoms of liver problems. These include nausea, tiredness, itching, tenderness in the right upper abdomen, and flu-like symptoms.

In addition, the following side effects have been reported: anxiety, blurred vision, colitis, confusion, decreased levels of sodium in the blood, depression, fluid in the lungs, hair loss, hallucinations, increased levels of potassium in the blood, insomnia, low blood cell counts, menstrual disorder, palpitations, pancreatitis, ringing in the ears, severe increase in blood pressure, tingling sensation, unusual headache with stiff neck (aseptic meningitis), vertigo.

More common, but less serious side effects reported with VIOXX have included the following:

Upper and/or lower respiratory infection
and/or inflammation
Headache
Dizziness
Diarrhea
Nausea and/or vomiting
Heartburn, stomach pain and upset
Swelling of the legs and/or feet
High blood pressure
Back pain
Tiredness
Urinary tract infection.

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These side effects were reported in at least 2% of osteoarthritis patients receiving daily doses of VIOXX 12.5 mg to 25 mg in clinical studies.

The side effects described above do not include all of the side effects reported with VIOXX. Do not rely on this leaflet alone for information about side effects. Your doctor or pharmacist can discuss with you a more complete list of side effects. Any time you have a medical problem you think may be related to VIOXX, talk to your doctor.

What else can I do to help manage my arthritis pain?

Talk to your doctor about:

- Exercise
- Controlling your weight
- Hot and cold treatments
- Using support devices.

What else should I know about VIOXX?

This leaflet provides a summary of certain information about VIOXX. If you have any questions or concerns about VIOXX, osteoarthritis, rheumatoid arthritis or pain, talk to your health professional. Your pharmacist can give you an additional leaflet that is written for health professionals.

Do not share VIOXX with anyone else; it was prescribed only for you. It should be taken only for the condition for which it was prescribed.

Keep VIOXX and all medicines out of the reach of children.

Inactive Ingredients:

Oral suspension: citric acid (monohydrate), sodium citrate (dihydrate), sorbitol solution, strawberry flavor, xanthan gum, sodium methylparaben, sodium propylparaben.

Tablets: croscarmellose sodium, hydroxypropyl cellulose, lactose, magnesium stearate, microcrystalline cellulose, and yellow ferric oxide.

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