

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

You should read this information before you or your child start taking VIOXX\*. Also, read the leaflet each time you refill a prescription, in case any information has changed. This leaflet provides only a summary of certain information about VIOXX. The 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 talking with your doctor about your condition or treatment. If you have questions about VIOXX ask your doctor or pharmacist.

**What is VIOXX?**

VIOXX is a prescription medicine called a COX-2 selective, nonsteroidal anti-inflammatory drug (NSAID). (See section "What is VIOXX used for?")

**Who should not take VIOXX?**

Do not take VIOXX if you or your child:

- have had an allergic reaction such as asthma attacks (wheezing), hives, or swelling of the throat and face to aspirin or other medicines called non-steroidal anti-inflammatory drugs (NSAIDs). There are many NSAID medicines. Ask the doctor or pharmacist for a list of medicines that contain NSAIDs if you are not sure.
- are allergic to rofecoxib, the active ingredient of VIOXX, or to any other ingredients in VIOXX. See the end of this leaflet for a complete list of ingredients in VIOXX.

**What are the possible side effects of VIOXX?**

Serious but rare and potentially life-threatening side effects that have been reported in patients taking VIOXX include:

- Serious stomach problems, such as stomach and intestinal bleeding, can happen with or without warning symptoms. These problems, if serious, could lead to hospitalization or death. Although this does not happen often, you should watch for the signs and symptoms (for instance, stomach burning, vomiting blood, or if there is blood in the bowel movement or it is black and sticky like tar). Call your doctor right away if you or your child have any of these serious side effects.
- Serious allergic reactions include the symptoms and signs of swelling of the face, lips, tongue; trouble breathing such as chest tightness or shortness of breath; trouble swallowing; hives; wheezing; or shock (loss of blood pressure and consciousness). Get emergency help right away if you get any of these symptoms or signs. Serious skin reactions have also been reported.
- Heart attacks and other serious cardiovascular events, such as blood clots in your body have been reported in patients taking VIOXX.
- Serious kidney problems can happen, including acute (sudden) kidney failure and worsening of chronic kidney failure.

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- Severe liver problems, including hepatitis, jaundice and liver failure, can occur. Call your doctor if you or your child gets any of these symptoms of liver problems. These include: nausea; itching; pain in the right upper abdomen; yellow skin or eyes; or flu-like symptoms.

Your doctor may do blood tests and check you or your child for problems that may happen during treatment with VIOXX.

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

- Respiratory infections
- Headache
- Dizziness
- Diarrhea
- Nausea, vomiting and upset stomach
- Heartburn
- Stomach pain
- Swelling of the legs and/or feet
- High blood pressure
- Back pain
- Tiredness
- Urinary tract infection.

In addition, the following side effects have been reported: anxiety, blurred vision, colitis, confusion, constipation, 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, skin reactions caused by sunlight, tingling sensation, unusual headache with stiff neck (aseptic meningitis), vertigo, worsening of epilepsy.

These are not all the side effects reported with VIOXX. Do not use this leaflet alone for information about side effects. Your doctor or pharmacist can talk to you about other side effects. Any time you or your child have a medical problem you think may be related to VIOXX, talk to your doctor.

### **What is VIOXX used for?**

VIOXX is used in adults for:

- relief of the pain and inflammation (swelling and soreness) of osteoarthritis (arthritis from wear and tear on your bones and your joints)
- relief of the pain and inflammation of rheumatoid arthritis in adults (arthritis caused by a condition where your immune system attacks your joints)
- management of short-term pain
- treatment of menstrual pain (pain during women's monthly periods)
- treatment of migraine headache attacks with or without aura.

VIOXX is used in children and adolescents, of at least 2 years of age and who weigh at least 10 kg (22 lbs.) to help relieve:

- the signs and symptoms of pauciarticular or polyarticular Juvenile Rheumatoid Arthritis (JRA). VIOXX has not been studied in children with systemic type JRA.

VIOXX has not been studied in children less than 2 years old or with body weight less than 10 kg (22 lbs.).

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

Tell your doctor about all your or your child's medical conditions including if you or your child have or have had:

- an allergic reaction to aspirin or other NSAIDs
- asthma (a small number of patients with asthma have reactions to aspirin or other NSAIDs)
- stomach problems such as ulcers or bleeding
- kidney disease
- liver disease
- angina (for instance, chest, arm, or jaw pain), a heart attack, or a blocked artery in the heart
- heart failure
- high blood pressure

Tell your doctor if you or your child are:

- pregnant or plan to become pregnant. VIOXX may harm your unborn baby if you take it in late pregnancy. If you take VIOXX while you are pregnant, ask your doctor how you can be on the VIOXX Pregnancy Registry.
- breast-feeding or plan to breast-feed. It is not known if VIOXX passes into your milk and if it can harm your baby. You should discuss with your doctor whether or not to take VIOXX if you are breast-feeding.

Tell your doctor about:

- any other medical problems or allergies you or your child have now or have had.
- all the medicines you or your child take including prescription and non-prescription medicines, vitamins, and herbal supplements.

Tell your doctor right away if you or your child develop:

- serious stomach problems such as ulcer or bleeding symptoms (for instance, stomach burning, vomiting blood, or if there is blood in your bowel movement or it is black and sticky like tar).
- unexplained weight gain or swelling of the legs, feet, and/or hands.
- skin rash or allergic reactions. If you or your child have a severe allergic reaction, get medical help right away.

### **Can VIOXX be taken with other medicines?**

Tell your doctor about all of the other medicines you or your child are taking or plan to take while you or your child are on VIOXX, even other medicines that you can get without a prescription, including vitamins and herbal supplements. VIOXX and certain other medicines can affect each other causing serious side effects. Keep a list of the medicines you or your child take. Show the list to your doctors and pharmacists each time you get a new medicine. They will tell you if it is safe to take VIOXX with other medicines. Especially tell your doctor if you or your child are taking:

- or have taken warfarin (Coumadin®) or any other similar blood thinner within the past 10 days
- 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 or your child take both aspirin and VIOXX, there may be a higher chance of serious stomach problems than if VIOXX is taken alone. If you or your child are taking aspirin for prevention of heart attack or stroke, you or your child should not stop taking aspirin without talking to your doctor.

### **How should VIOXX be taken?**

- Take VIOXX exactly as prescribed by the doctor. The dose will depend on the condition being treated and other medical problems you or your child may have. Do not change the dose of VIOXX or take extra doses unless the doctor has told you to.

- VIOXX may be taken with or without food.
- If you or your child miss a dose of VIOXX by a few hours, take it as soon as you remember. If it is close to the next dose, do NOT take the missed dose.
- If you or your child take too much VIOXX, call the doctor, pharmacist, or poison control center right away.

**How should I store VIOXX?**

- Store VIOXX at room temperature, 59° to 86°F (15° to 30°C).
- Safely throw away VIOXX that is out of date or no longer needed.
- Keep VIOXX and all medicines out of the reach of children.

**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 talk to your health professional. Your doctor or pharmacist can give you an additional leaflet that is written for health professionals. This leaflet is also available at [www.vioxx.com](http://www.vioxx.com).

Medicines are sometimes prescribed for conditions other than those described in patient information leaflets. Do not use VIOXX for a condition for which it was not prescribed. Do not give VIOXX to other people even if they have the same symptoms you have. It may harm them.

**What are the ingredients in VIOXX?**

Active Ingredient: rofecoxib

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.

**Rx Only**

Issued August 2004

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