VIOXX[®]: WHAT SHOULD WE TELL OUR PATIENTS?

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In order to provide better care to patients, doctors of chiropractic should be informed about adverse affects of certain drugs. Presently, questions are being raised about cardiovascular risks, such as increased deaths due to stroke or myocardial infarction, which may be caused from drugs in the same class as Vioxx[®].¹ Therefore, it is important for doctors of chiropractic to stay apprised of information that may affect the health of their patients, such as COX-2 inhibitor usage.

Vioxx[®] information for doctors:

Vioxx[®] (rofecoxib) is a prescription drug that was originally FDA approved in May 1999,² and was concurrently being tested in clinical trials. The researchers for Merck, the pharmaceutical company that makes Vioxx[®], had noticed a trend in the data collected in these trials. Based upon results that showed an increase risk in cardiovascular related incidents,³ Merck decided to withdraw this drug from the market on September 30, 2004.^{4,5}

Regardless of the controversy over whether the FDA or Merck should have withdrawn Vioxx[®] earlier or not,⁶ patients may be faced with questions about their health and the doctor of chiropractic may be able to assist them in finding answers.

Chiropractic patients who are being managed for conditions that this drug may be prescribed for (such as osteoarthritis, rheumatoid arthritis, menstrual pain, and migraine headaches) may be concurrently managed and may not inform their doctor that they have been taking or are continuing to take Vioxx[®]. Therefore, the doctor of chiropractic may wish to consider informing patients about recent research findings and their impact on patients' health.

Active ingredient: rofecoxib.

Action: a COX-2 inhibitor, a nonsteroidal anti-inflammatory drug (NSAID).

Distribution: prescription only.

Rofecoxib was typically prescribed to adults for the following reasons:

- relief of the pain and inflammation from osteoarthritis or rheumatoid arthritis
- treatment of menstrual pain
- treatment of migraine headache attacks with or without aura.

Patients may report side effects from taking rofecoxib. The Merck leaflet,⁷ released August 2004, reports potential side effects of rofecoxib: "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.

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."

In addition to those listed as serious, according to Merck, other side effects reported with rofecoxib include the following: respiratory infections, headache, dizziness, diarrhea, nausea, vomiting, heartburn, stomach pain, swelling of the legs and/or feet,

high blood pressure, back pain, tiredness, urinary tract infection, 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, and worsening of epilepsy.⁷

New research suggests a possible cause for the increase in cardiovascular events, such as myocardial infarction and stroke, due to the prolonged intake of COX-2 inhibitors.⁸ The COX-2 enzyme is normally responsible for creating fatty acids, such as prostacyclin, which is thought to help protect against cardiovascular events. Drugs that inhibit COX-2 may interfere with the production of the protective fatty acids and thus, may increase the risk for stroke and heart attack through increasing the incidence of atherosclerosis.⁸

Additional information can be found at:

Merck

<http://www.vioxx.com/rofecoxib/vioxx>

FDA

<http://www.fda.gov/cder/drug/infopage/vioxx>

Vioxx®: information for patients

Why can Vioxx no longer prescribed to me?

Merck, the pharmaceutical company that makes Vioxx, has withdrawn this drug from the market. Researchers had noticed a trend in the data collected in their research trials and decided to withdraw the drug from the market on September 30, 2004 for patient safety reasons.^{9,10}

Will I have long-term damage from taking this drug?

At the moment, it is uncertain what the long term or lasting effects might be. The decision to withdraw this drug was based on the findings of a research trial. In this trial, it was observed that there was an increased risk for serious problems, such as heart attacks and strokes, for patients with 18 months of continuous treatment with Vioxx compared to patients not taking this drug (taking a placebo—a sugar pill).^{2,3,10}

What should I do with any remaining pills from my prescription?

It has been recommended that patients contact their prescribing physician to discuss discontinuing the use of Vioxx.^{5,9}

What are my options for pain control?

Patients should discuss with their health care providers what options that they may have for control-

ling pain. In addition to pharmaceuticals, other pain control methods that may be considered are manual therapies, acupuncture, supplements, exercise, etc.^{11–15} Because each patient has different clinical needs, these should be discussed with the health care provider.¹⁰

Are there health risks for other drugs, including those that are similar to Vioxx?

Currently other similar drugs are under investigation for what possible reactions they might have. As the FDA Commissioner recently stated, “All of the NSAID drugs have risks when taken chronically . . .”³ Patients need to be reminded that all drugs have side effects.¹⁰ Patients should be informed of risks prior to beginning any treatment regimen.

Where can I get more information about Vioxx?

The following websites may be helpful in providing more information:

Merck information for patients http://www.vioxx.com/rofecoxib/vioxx/consumer/patient_important_information.jsp

FDA questions and answers

<http://www.fda.gov/cder/drug/infopage/vioxx/vioxxQA.htm>

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