



**U.S. Naval Hospital, Okinawa, Japan  
PSC 482  
FPO AP 96362**

The Merck Corporation announced a voluntary worldwide withdrawal of VIOXX (rofecoxib) on September 30, 2004. Below are some questions and answers concerning the reasons for withdrawal and what you can do if you were affected.

**1. What is VIOXX?**

VIOXX is a COX-2 selective nonsteroidal anti-inflammatory drug (NSAID). VIOXX is also related to the nonselective NSAIDs, such as Ibuprofen (Motrin, Advil, Nupren, Rufen) and Naproxen (Naprosyn, Aleve, Anaprox, Naprelan. VIOXX is a prescription medicine used to relieve signs and symptoms of arthritis, acute pain in adults, and painful menstrual cycles.

**2. Why is Merck withdrawing VIOXX?**

Merck & Co., Inc., is voluntarily withdrawing VIOXX<sup>®</sup> (rofecoxib) effective immediately based on new data from a 3-year clinical study. In this study, there was an increased risk for cardiovascular (CV) events, such as heart attack and stroke, in the patients taking VIOXX 25 mg compared to those taking placebo (sugar pill). There was an increased risk beginning after 18 months of treatment.

**3. Did the Food and Drug Administration require this action?**

No, Merck made this decision independent of input from the FDA. The Agency has not had an opportunity to review the data from the study that was stopped in the depth that Merck has, but agrees with the company that there appear to be significant safety concerns for patients, particularly those taking the drug chronically.

**4. What should I do if I am currently taking VIOXX?**

Although the risk that an individual patient will suffer a heart attack or stroke related to VIOXX is very small, we are urging our patients to stop taking the medication and obtain the substitute. The U.S. Naval Hospital and 18<sup>th</sup> Medical Group are no longer dispensing VIOXX prescriptions. The current prescriptions for VIOXX will automatically be changed to an alternative. You may call (643-7557 USNH or 630-4591 Kadena Clinic) or visit the pharmacy to have the substitute prescription filled. Please contact your primary care clinic if you are concerned about alternative treatment.

**5. What are the likely long-term health effects, if any, of taking this product?**

The new study shows that VIOXX may cause an increased risk in cardiovascular events such as heart attack and strokes during chronic, long-term use.

**6. Will VIOXX be recalled by the FDA?**

The FDA did not request a recall of VIOXX. Merck is voluntarily withdrawing this product from the market.

7. What should I do with my VIOXX tablets?

Pay Patients at the U.S. Naval Hospital may return unused, including opened, portions of VIOXX to the business office for reimbursement on that current prescription. In order to be reimbursed you will need to return the prescribed bottle of VIOXX (used or unused) and reimbursements will not be given without this proof of purchase. For questions concerning reimbursement for your current prescription, you may contact the business office at 643-7738/7438. All other beneficiaries may return the tablets to the pharmacy when picking up their new prescriptions.

8. Where can I get more information?

If you have other questions or concerns, you may contact the U.S. Naval Hospital Pharmacy at 643-7557, the Kadena Clinic Pharmacy at 630-4591, or contact your primary care clinic. You can obtain more information from Merck at: [www.merck.com](http://www.merck.com) and [www.VIOXX.com](http://www.VIOXX.com).