

Drug Alert

Important Drug Information



April 9, 2009

Dear Client,

The HealthTrans clinical team works proactively to provide you with important FDA drug alerts as they are released. With your best interest in mind, we monitor all relevant changes to the status of drugs to ensure that you are well informed of issues that may affect your prescription benefit and members' overall health. We recommend that you share this information within your setting as appropriate.

Genentech Announces Voluntary Withdrawal of Raptiva from the U.S. Market

Genentech, Inc., announced today a phased voluntary withdrawal of the psoriasis drug Raptiva® (efalizumab) from the U.S. market. The company's decision is based on the association of Raptiva with an increased risk of progressive multifocal leukoencephalopathy (PML), a rare and usually fatal disease of the central nervous system. Raptiva is indicated for the treatment of chronic moderate-to-severe plaque psoriasis in adults 18 years or older who are candidates for systemic therapy or phototherapy.

Effective immediately, physicians should not issue prescriptions for Raptiva for any new patients and should promptly contact patients currently receiving Raptiva to assess the most appropriate treatment alternatives. Raptiva will no longer be available after June 8, 2009. This transition period is intended to allow patients who are currently taking Raptiva enough time to work with their doctors to appropriately discontinue use of Raptiva. Because of the potential for severe psoriasis worsening with abrupt discontinuation of Raptiva, it is important that patients talk with their doctor before stopping treatment.

The Raptiva prescribing information was updated in October 2008 to include a boxed warning on the risk of serious infections, including PML, in patients receiving Raptiva. The Raptiva prescribing information was further updated in March 2009 to include additional information on the risk of PML and a new Medication Guide for patients.

There have been three cases of diagnosed PML in patients receiving Raptiva and one patient treated with Raptiva who developed progressive neurologic symptoms and died of unknown cause. It is not known whether other, unreported cases have occurred. Healthcare provider letters were issued to inform prescribers about the risk of PML with Raptiva as these cases were identified.

The company has taken immediate steps to inform potential prescribers, patients, clinical trial investigators, and distributors of the decision to withdraw Raptiva from the market in the United States. Copies of these letters have been posted today to the Genentech web site <http://www.gene.com> and are available by clicking the Raptiva link at <http://www.gene.com/gene/products/information/>. Physicians with questions about Raptiva use may contact Genentech Medical Communications at 1-800-821-8590.

The company's actions have been taken after consultation with the U.S. Food and Drug Administration.

Members who are currently taking Raptiva should contact their physician to discuss alternative treatment options.

Thank you for your attention to this important message.