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Natalizumab (Tysabri®) Returns to Market

THE ISSUE

On June 5, 2006, the FDA approved the resumption of the marketing of natalizumab. A restricted distribution system and risk management plan will be implemented to ensure its appropriate use and to monitor for adverse events.

THE DRUG

Natalizumab is a monoclonal antibody marketed under the brand name Tysabri® for the treatment of relapsing forms of multiple sclerosis (MS). It is supplied in 300 mg single-use vials for intravenous infusion. Therapy is administered intravenously over one hour every four weeks.

THE RISK

Natalizumab was withdrawn from the market by the manufacturer, Biogen-Idec, in February 2005 after three patients in clinical trials developed progressive multifocal leukoencephalopathy (PML), a rare, opportunistic, viral brain infection that causes demyelination of neurons.

WHAT YOU NEED TO KNOW

Natalizumab is currently approved as monotherapy only in patients who have not responded to or have not

tolerated other therapies. The patients who developed PML were receiving other immunosuppressants or immunomodulators, but it is not known whether these agents contributed to the development of PML. Prescribers must register with the risk-management program, the TOUCH™ program. Distribution and administration of natalizumab are restricted to pharmacies and infusion centers registered with the TOUCH™ program. Pharmacies and infusion staff are required to register with the TOUCH™ program.

WHAT TO TELL YOUR PATIENTS

Natalizumab is not a cure for MS. Patients must register with the TOUCH™ program and be advised of the risks and potential benefits of natalizumab. It is not known whether the risk of developing PML is reduced by the use of natalizumab as monotherapy. The use of natalizumab may increase the risk of developing unusual, opportunistic infections. Patients receiving natalizumab will be monitored closely by their physicians every three months during the entire course of therapy for the development of PML or other opportunistic infections. Patients should be sure that any physician or pharmacist caring for them is aware of all the medications they are taking.

RESOURCES

Natalizumab prescribing information: <http://www.biogenidec.com/site/TYSABRI-PI-MedGuide.pdf>

Tysabri® Information Center: www.tysabri.com

Summary of TOUCH™ risk management plan: <http://www.fda.gov/cder/drug/infopage/natalizumab/RiskMAP.pdf>

PML information page: <http://www.ninds.nih.gov/disorders/pml/pml.htm>

Question and answer page: http://www.fda.gov/cder/drug/infopage/natalizumab/QA_6_2006.htm

February 2005, Public Health Advisory: <http://www.fda.gov/cder/drug/advisory/natalizumab.htm>

DISCLAIMER

This publication is intended to provide key practical information regarding this drug product in a brief format. It does not contain sufficient information upon which to base formulary or other medication use policy decisions.

