FDA News

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FDA Requests Boxed Warning for Contrast Agents Used to Improve MRI Images

The U.S. Food and Drug Administration (FDA) has asked manufacturers to include a new boxed warning on the product labeling of all gadolinium-based contrast agents which are used to enhance the quality of magnetic resonance imaging (MRI).

The requested warning would state that patients with severe kidney insufficiency who receive gadolinium-based agents are at risk for developing a debilitating, and a potentially fatal disease known as nephrogenic systemic fibrosis (NSF). In addition, it would state that patients just before or just after liver transplantation, or those with chronic liver disease, are also at risk for developing NSF if they are experiencing kidney insufficiency of any severity.

"FDA has been carefully monitoring potential safety signals related to these contrast agents after receiving reports about the risk of this potentially life-threatening disease," said Steven Galson, M.D., M.P.H., director of FDA's Center for Drug Evaluation and Research. "This latest action demonstrates FDA's continuing vigilance about ensuring the safety of drug products once they enter the marketplace."

Patients with NSF develop thickening of the skin and connective tissues that inhibits their ability to move and may result in broken bones. Other organs are at risk of thickening as well. The cause of NSF is not known and there is no consistently effective treatment of this condition.

FDA first notified health care professionals and the public about the gadolinium-related risks for NSF in June 2006 . Information on the risks was updated in December.

Gadolinium-based contrast agents are commonly used to improve the visibility of internal structures when patients undergo an MRI. Five gadolinium-based contrast agents have been approved for use in the United States: Magnevist (gadopentetate dimeglumine), Ominiscan (gadodiamide); OptiMARK (gadoversetamide); MultiHance;(gadobenate dimeglumine);and Prohance (gadoteridol).

Reports have identified the development of NSF following single and multiple administrations of the gadolinium-based contrast agents. The reports have not always identified a specific agent. Omniscan was the most commonly reported agent, when a specific agent was identified, followed by Magnevist and OptiMARK.

NSF also has developed after the sequential administration of Omniscan and MultiHance and Omniscan and ProHance. Because reports incompletely describe exposure to gadolinium-based contrast agents, it is not possible to know if the extent of risks for developing NSF is the same for all agents.

Patients should be screened for kidney problems prior to receiving one of these imaging agents. The recommended dose should not be exceeded and enough time should elapse to ensure that a dose has been eliminated from the body before the agent is used again.

There have been no reports of NSF among patients with normal kidney function or those with mild-to-moderate kidney insufficiency.

Bayer Schering Pharma, Berlin, Germany, manufactures Magnevist; GE Healthcare, Chalfont St. Giles, U.K., is the maker of Omniscan; OptiMARK is manufactured by Mallinckrodt, Inc., Hazelwood, Mo.; and ProHance and Multihance are made by Bracco Diagnostics Inc., Princeton, N.J.

For more information see www.fda.gov/cder/drug/infopage/gcca/default.htm.

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