

Fairway Imaging, LLC /dba/PREMIER MRI 4U

Gadolinium Warning and Consent

To our patients: On 5/23/2007, U.S. Food and Drug Administration (FDA) has asked manufacturers of gadolinium-based contrast agents to include a new warning. The following is from the FDA web page regarding t his on 5/30/2007. Please carefully read this, and let us know if you have any questions or concerns. Thank you or choosing PREMIER MRI 4U

Your physician has ordered your MRI study with contrast. Please read the information below, and let us know if you have any questions whatsoever. You should also have been handed pharmaceutical information about the Gadolinium that we use, Prohance by Bracco.

The contrast media is extremely well tolerated by the vast majority of patients in whom they are injected. Adverse reactions are encountered with a much lower frequency than is observed after iodinated contrast. The frequency of all adverse events after an injection of .01 or .02 mmol/kg ranges from 0.07-2.4 %. The vast majority of these reactions are mild including coldness at the injection site, nausea with or without vomiting, headache, warmth or pain at the injection site, paresthesias, dizziness and itching. Reactions resembling 'allergic' response are very unusual and vary in frequency from 0 .004-.07 %. A rash, hives or urticaria are most frequent in this group, and vary rarely there may be bronchospasm. Severe, life-threatening anapylactoid reactions are also rare (0.001 – 0.01%), Fatal reactions to gadolinium agents are very rare. IF YOU HAVE HAD A REACTION TO CONTRAST MEDIA IN THE PAST, PLEASE NOTIFY OUR STAFF AND THE MRI TECHNOLOGIST AT ONCE BEFORE STARTING THE SCAN!

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, this also includes 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.

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.

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 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 (gadodiamiderisks) for developing NSF is the same for all agents.

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

I have read the above and understand the information provided.

I agree to having gadolinium administered for my MRI study today.

I decline the administration (injection) of gadolinium for my MRI today and in doing so I realize that the results of this MRI study may be compromised (lessened).

Patient Name: \_\_\_\_\_ Signature: \_\_\_\_\_

If signature is of the patient's legal guardian, please indicate and give your relationship if any to the patient:

\_\_\_\_\_ Date: \_\_\_\_\_