Dotarem approved for nervous system MRIs

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(HealthDay)—Dotarem (gadoterate meglumine) has been approved by the U.S. Food and Drug Administration as a contrast agent for use in MRIs of the brain, spine and other parts of the central nervous system.

Approved for people two years and older, the imaging agent helps radiologists detect lesions and other abnormalities. Dotarem and similar agents all carry a boxed label warning of the risk of nephrogenic systemic fibrosis, a rare yet dangerous condition that can develop in people with kidney disease, the FDA said in a news release. The condition is characterized by pain and thickening of the skin.

Dotarem's safety and effectiveness were evaluated in clinical studies involving 245 adults and 38 children with suspected abnormalities of the central nervous system. All side effects were rare, the agency said, but the most common ones included nausea, headache, a burning sensation, and injection-site pain and coldness.

Dotarem is marketed by Guerbet LLC, based in Bloomington, Ind.

More information: The FDA has more about this approval.