

Reports of fatal anaphylaxis with IV iron products

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(HealthDay)—Fatal anaphylaxis cases have been reported with

administration of intravenous (IV) iron products, according to a letter to the editor published online Aug. 29 in the *American Journal of Hematology*.

Lynda McCulley, Pharm.D., from the U.S. Food and Drug Administration in Silver Spring, Md., and colleagues discuss reports of fatal hypersensitivity reactions, including anaphylaxis, in association with IV iron agents.

The researchers note that in the past five years, the FDA has received 49 reports of death temporally associated with IV iron administration, of which 30 were determined to be anaphylaxis. Furthermore, 79 cases of anaphylactic reactions associated with ferumoxytol administration were identified from the FDA Adverse Events Reporting System database in March 2015, of which 18 were fatal. Based on these data, the FDA strengthened an existing warning and approved a Boxed Warning regarding these risks for ferumoxytol. A significant modification was made to the ferumoxytol Dosage and Administration section, with a recommendation to dilute the drug, and slow its administration. Reports of fatal anaphylaxis reactions with symptom onset during or shortly after administration have been reported for all currently marketed IV iron products.

"We remain concerned about the risk of fatal anaphylaxis with IV iron products, which may differ among products," the authors write.

"Although such reactions may be rare, they have the potential to affect the benefit-risk balance of these products, especially when such reactions do not occur with oral iron preparation."

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