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Oncology Drug Gets Black Box Warning

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Review

WASHINGTON -- A black box warning -- which includes cautions about potentially fatal renal, hepatic, and gastrointestinal damage -- has been added to the labeling for the oncology drug deferasirox (Exjade), the FDA announced.

The risk of renal impairment or failure, hepatic impairment or failure, and gastrointestinal hemorrhage is particularly likely in patients who:

- Are older
- Are at high risk for myelodysplastic syndromes
- Have underlying renal or hepatic impairment
- Have low platelet counts

The FDA conducted an investigation of the drug after reports of adverse events and death in patients with myelodysplastic syndromes. (See [FDA Tracking Possible Problem with Iron Chelator](#))

The new label urges careful monitoring of creatine levels, particularly in patients at risk for renal impairment, as well as serum transaminases and bilirubin.

Additional adverse events added to the drug's warning label include rash and weakened effectiveness when taken with cholestyramine.

Negative side effects of the drug also include abdominal pain, diarrhea, proteinuria, hypersensitivity reactions, leukocytoclastic vasculitis, urticaria, alopecia, increased creatine levels, nausea, and vomiting.

Deferasirox is manufactured by Novartis.

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