FDA issues alert about HIV drug Prezista

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The U.S. Food and Drug Administration has issued an alert concerning reports of liver injury in patients taking Prezista.

The FDA said Prezista (darunavir), an anti-retroviral drug used to treat for the human immunodeficiency virus HIV, is suspected of contributing to several hepatic events, including liver failure, destruction of liver tissue, cirrhosis, hepatitis and jaundice.

Healthcare professionals were advised to conduct appropriate laboratory testing prior to and after starting patients on Prezista and to be alert for symptoms of hepatotoxicity, including unexplained fatigue, anorexia, nausea, jaundice, dark urine and liver tenderness.

Patients with chronic hepatitis B or C or those who have pretreatment elevations of liver function tests should be monitored more frequently.

The FDA said it worked with the drug's manufacturer -- Tibotec Therapeutics Inc. of Bridgewater, N.J. -- to include the new hepatotoxicity information on the drug's label.