Rare, Serious Liver Disease Associated With HIV Drug Videx EC

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The nucleoside analogue Videx EC (didanosine) is associated with a liver disorder called non-cirrhotic portal hypertension, according to a warning issued by the U.S. Food and Drug Administration (FDA). Though this form of liver disease can be serious, it is a rare occurrence among people living with HIV and using Videx EC and the drug's benefits "continue to outweigh potential safety risks," the agency said.

Videx, approved in 1991, was the second drug to become commercially available to treat HIV. Originally made as a buffered tablet or powder, once-daily Videx EC capsules were approved in 2000. Generic versions of Videx EC were approved in 2004. Though Videx EC is used less today than in years past, notably among those starting HIV treatment for the first time, it is still prescribed for certain patients. What's more, generic didanosine is frequently prescribed in many resource-poor countries.

The FDA said it received 42 reports of non-cirrhotic portal hypertension in the 18 years since the drug was first approved, with three patients needing liver transplants and four patients dying from bleeding or liver failure. Though the FDA contends that it is difficult to draw concrete conclusions from a small number of case reports, the agency says enough data exist to suggest an association between Videx EC use and non-cirrhotic portal hypertension.

Bristol-Myers Squibb, Videx EC's manufacturer, has added the warning to the drug's package insert. According to the new warning, patients "should be monitored for early signs of portal hypertension during routine medical visits."

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