FDA Adds Warning of Hepatitis B Reactivation to Hepatitis C Treatment Labels

The black-box warning, which applies to all hep C medications, is the most serious the health agency can give.

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The U.S. Food and Drug Administration (FDA) has issued a black-box warning of the reactivation of hepatitis B virus (HBV) during treatment for hepatitis C virus (HCV). The black-box warning label, the most serious the FDA can issue, applies to all direct-acting antivirals for hep C treatment.

The FDA has identified 24 individuals with HBV and HCV who experienced reactivation of their hep B infection while undergoing treatment for hep C. This figure represents only those cases reported to the FDA or identified in medical literature, so there are likely others.

The FDA’s warning comes on the heels of new hep C treatment guidelines issued by the American Association for the Study of Liver Diseases and the Infectious Diseases Society of America, which recommend hep B testing for all people beginning hep C treatment.

The FDA also advises health care professionals to conduct such screening and to monitor individuals who test positive for hep B flare-ups or reactivation during hep C treatment as well as during follow-up after treatment.

The agency recommends that people considering hep C treatment disclose any history of hep B infection or other liver problems to their physician before starting such treatment. It is important not to stop taking hep C therapy without first talking with a health care professional, the FDA stresses.

People with hep C should contact their health care professional immediately if they develop fatigue, weakness, loss of appetite, nausea and vomiting, yellow eyes or skin, or light-colored stools, since these may indicate serious liver problems.

Researchers do not yet understand why the hep B flare-ups take place during hep C treatment.

To read the FDA announcement, click here.