

FDA Drug Safety Communication: Serious Skin Reactions in Incivek users

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ISSUE: FDA received reports of serious skin reactions, some fatal, in patients taking the hepatitis C drug Incivek (telaprevir) in combination with the drugs peginterferon alfa and ribavirin (Incivek combination treatment). Some patients died when they continued to receive Incivek combination treatment after developing a worsening, or progressive rash and systemic symptoms (symptoms affecting the entire body).

FDA is adding a boxed warning to the Incivek drug label stating that Incivek combination treatment must be immediately stopped in patients experiencing a rash with systemic symptoms or a progressive severe rash.

BACKGROUND: Incivek is a hepatic C virus NS3/4A protease inhibitor indicated in combination with peginterferon alfa and ribavirin for the treatment of genotype 1 chronic hepatitis C in adult patients with compensated liver disease, including patients who have cirrhosis, are treatment-naïve, or who have been previously received interferon-based treatment.

INCIVEK USE IN DOD: A Pharmacovigilance Center (PVC) analysis of DOD data conducted in response to this FDA message found approximately 280 individuals and 529 (total) prescriptions for Incivek since market inception (May 2011).

RECOMMENDATIONS: Make sure your patients know that rash may occur with Incivek combination treatment, and explain the signs and symptoms of severe skin reaction and when to seek care.

If serious skin reactions occur, all three components of Incivek combination treatment, including peginterferon alfa and ribavirin, must be immediately discontinued, and the patient should receive urgent medical care. Consideration should also be given to stopping any other medications that may be associated with serious skin reactions.

The entire FDA Drug Safety Communication is attached and also available at:
<http://www.fda.gov/Drugs/DrugSafety/ucm332731.htm>

Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program at:
www.fda.gov/MedWatch/report.htm

QUESTIONS OR ADDITIONAL INFORMATION: Send requests for additional information regarding this alert or the analysis conducted by the Pharmacovigilance Center (PVC) to:
otsq.pvc@amedd.army.mil