New Warning on Intelence

August 26, 2009 By Paul Dalton

The FDA has issued a new safety warning for the NNRTI Intelence (etravirine). The text reads:

August 2009

Dear Healthcare Professional:

Tibotec Therapeutics, in cooperation with the U.S. Food and Drug Administration, would like to inform you of an important safety update to the Severe Skin Reactions WARNINGS AND PRECAUTIONS section (5.1) of the INTELENCE (etravirine) tablets prescribing information.

Specifically, the existing Warning and Precaution regarding Severe Skin Reactions has been strengthened to reflect that there have been postmarketing reports of:

? fatality due to toxic epidermal necrolysis

? hypersensitivity reactions, sometimes accompanied by hepatic failure

Additionally, Guidance has been added that INTELENCE should be immediately discontinued when signs and symptoms of severe skin or hypersensitivity reactions develop. Given the clinical relevance of these adverse reactions, the following information regarding severe skin and hypersensitivity reactions has been included in the INTELENCE Prescribing Information

These kinds of reactions have been seen with other drugs in this class.

Intelence (aka worst HIV drug name ever) is a second line NNRTI for use in people whose HIV has developed resistance to other NNRTIs, like Sustiva (efavirenz) and Viramune (niravapine).

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http://beta.docker.poz.com/blog/new-warning-on-intel