New Intelence Prescribing Information Warns of Severe Rash Risk

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The prescribing information for Intelence (etravirine) has been updated to reflect warnings of rare—but potentially life-threatening—skin reactions, including Stevens-Johnson syndrome. Systemic hypersensitivity reactions have also been reported and are characterized by rash, flulike symptoms and sometimes organ problems, including liver failure.

Intelence is a non-nucleoside reverse transcriptase inhibitor approved for people who have become resistant to other HIV medications. Studies show that it is generally a safe, tolerable and effective medication for the majority of people who use it.

The Food and Drug Administration (FDA) occasionally requires pharmaceutical companies to update their prescribing information to reflect new information regarding a drug's safety or effectiveness. Tibotec, which makes Intelence, said that 1.3 percent of people taking Intelence developed moderate to severe rashes in clinical trials, compared with 0.2 percent of people who received a placebo in those trials.

Rashes typically appeared within the first six weeks of therapy with Intelence. If the rash becomes severe, the prescribing information warns, individuals using the drug should contact their health care providers immediately to discuss possibly stopping Intelence.

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