

This is language in McNeil's Motrin label:

MOTRIN can cause Stevens-Johnson syndrome (SJS), and toxic epidermal necrolysis (TEN), which can be fatal. Patients should be informed about the signs and symptoms of serious skin manifestations and use of the drug should be discontinued at the first appearance of skin rash or any other sign of hypersensitivity.

McNeil published their Motrin label in the Physician's Desk Reference (PDR) every year from 1996-2005. In 2006, the FDA recommended the language above and McNeil agreed to put it in their Motrin label. Then, McNeil, for the first time ever chose not to publish their Motrin label in the PDR.

McNeil, as of February 2012, has never alerted U.S. doctors of these facts and this warning. McNeil has also never advised parents of this. McNeil knows that doctors across the country have continued recommending or administering Motrin/ibuprofen after the first appearance of skin rash or any other sign of hypersensitivity, even when their patients are getting or have been inflicted with these deadly diseases. McNeil has done nothing to educate U.S. doctors of these important facts.

[A link to the FDA's website where McNeil's never-published, never-disseminated label appears is:

http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.Label_ApprovalHistory]