

Acetaminophen May Cause Risk for Rare but Fatal Skin Reactions

On August 1, 2013, the FDA announced to health care professionals that acetaminophen carries a risk of causing rare but serious skin reactions. Acetaminophen is indicated as a pain reliever and fever reducer; it is a common ingredient in many prescription and over-the-counter medications. This reaction has been noted in first-time use and at any time during therapy.

The skin reactions include Steven—Johnson syndrome (SJS), toxic epidermal necrolysis (TEN), and acute generalized exanthematous pustulosis (AGEP). The reactions present as rash, reddening of the skin, blisters, and detachment of the outer surface of the skin; they can also be potentially fatal. If a patient is experiencing these symptoms, it is recommended that they stop using the product at the first sign of skin rash or reaction and seek immediate medical attention.

The reactions will manifest in different ways. AGEP is a non-life threatening reaction that is characterized by the rapid appearance of areas of red skin with pustules. It will usually start in a small area then manifest over a large area, and it can be accompanied by fever and elevated neutrophil counts. It will typically resolve within two weeks of stopping the causative medication. SJS and TEN are both more serious, life-threatening reactions that can result in death, and they will usually require hospitalization. SJS typically manifests over a small surface area of the skin, while TEN covers large portions of the body. They typically begin with flu-like symptoms, followed by rash, blistering, and detachment of the outer layer of the skin. Recovery from both SJS and TEN can take weeks to months, depending on the severity. Other possible complications include scars, skin pigmentation changes, internal organ damages, and blindness.

The FDA will require that a warning detailing the risk of serious skin reactions be added to the labels of prescription medications that contain acetaminophen, and they will request that such labels be added to over-the-counter products as well. Other medications used to treat fever and pain, such as NSAIDs, already contain the warning for these reactions on their drug labels. Health care professionals should be aware of the risk with use of acetaminophen and should consider acetaminophen ingestion when assessing patients with these potential drug-induced skin reactions.

References:

- FDA Drug Safety Communication: FDA warns of rare but serious skin reactions with the pain reliever/fever reducer acetaminophen. US Food and Drug Administration. Available at <http://www.fda.gov/Drugs/DrugSafety/ucm363041.htm>.
- Robert Lowes. Acetaminophen Poses Risk for Rare but Fatal Skin Reactions. Medscape. Available at <http://www.medscape.com/viewarticle/808807>.
- FDA Warns of Rare Acetaminophen Risk. US Food and Drug Administration. Available at <http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm363010.htm>.
- Sidoroff A. Acute generalized exanthematous pustulosis (AGEP). In: UpToDate, Mockenhaupt M (Ed). UpToDate: Waltham, MA, 2013.
- French LE. Toxic epidermal necrolysis and Stevens Johnson syndrome: our current understanding. Allergol In. 2006;55(1):9-16.
- Foster SC. Stevens-Johnson Syndrome. Medscape. Available at <http://emedicine.medscape.com/article/1197450-overview>.
- Cohen V. Toxic Epidermal Necrolysis. Medscape. Available at <http://emedicine.medscape.com/article/229698-overview>.