

### **Acetaminophen Linked to Rare, Serious Skin Reactions**

On August 2, 2013, the FDA announced that during a review of adverse events, a small number of cases of serious skin reactions such as Stevens-Johnson syndrome, toxic epidermal necrolysis, and acute generalized exanthematous pustulosis was reported in patients taking acetaminophen products. The reaction can occur upon the first dose of the drug, and after any subsequent dose at any time. During a rechallenge, some of the skin reactions were reoccurring or worsening. Some of these reactions have led to hospitalization and death. Although these reactions have also been associated with other types of analgesics such as NSAIDs, the FDA states that sensitivity to one type does not indicate sensitivity to another.

The FDA states that labeling for acetaminophen products is set to be revised to include the risk of rare but serious skin reactions and what to do if one should occur. Health care professionals are also being advised to speak with their patients about this side effect when counseling for acetaminophen (1).

Toxic epidermal necrolysis is a serious skin condition that causes the skin to turn red/purple and peel away from the body. Before any skin symptoms are seen, TEN and SJS often manifest as fever, flu-like illness, itching or burning in the eyes, patches of red, painful skin, bruises and blisters, and eventually the peeling skin, sores, swelling, and crusting on body mucosa. Stevens-Johnson syndrome is a more severe form of toxic epidermal necrolysis. These conditions are usually drug-induced, but can also be caused by an infection such as HIV (5).

Several reports have been published in various journals of acetaminophen-induced toxic epidermal necrolysis and Stevens-Johnson syndrome. One report involved a 40 year old lady who developed the problem after taking several doses of acetaminophen for fever. She developed maculopapular rash, stinging in her eyes, oral mucosal ulcerations, and high grade fever (2). Other reports included a case of toxic epidermal necrolysis “probably” induced by acetaminophen (3) and a 7 year old girl that developed toxic epidermal necrolysis following acetaminophen ingestion. A skin biopsy and acetaminophen rechallenge by an allergist confirmed her diagnosis (4).

Based on these findings, it is important for patients to be aware of the possibility of serious skin reactions when taking acetaminophen. Acetaminophen is an extremely widely used drug, and is considered relatively safe aside from its potential to cause harmful liver effects when used at high doses or over long periods of time. Patients need to be aware of other potential side effects, no matter how rare they might be.

#### **References:**

1. Traynor, Kate. “Acetaminophen Linked to Rare, Serious Skin Reactions.” ASHP Pharmacy News. Bethesda, MD. August 2, 2013. Available at: <http://www.ashp.org/menu/News/PharmacyNews/NewsArticle.aspx?id=3936>
2. Khawaja A, Shahab A, Hussain SA., Acetaminophen induced Steven-Johnson syndrome – toxic epidermal necrolysis overlap. Journal of the Pakistan Medical Association. 2012; 62(5): 524-527.
3. Bygum A, Gregersen JW, Buus SK. Acetaminophen-induced toxic epidermal necrolysis in a child. Pediatric Dermatology. 2004;21:236–8.
4. Aalevi A, Ben-Amitai D, Garty BZ. Toxic epidermal necrolysis associated with acetaminophen ingestion. Annals of Pharmacotherapy. 2000;34:32–4.

5. Stevens-Johnson Syndrome. Lexi-Drugs [database online]. Lexi-Comp, Inc; October 11, 2013

Prepared by: Alyssa Bartlett, Doctor of Pharmacy Candidate