



Acetaminophen: Drug Safety Communication - Association with Risk of Serious Skin Reactions

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FDA提醒醫療人員，acetaminophen可能造成罕見而嚴重的皮膚反應。Acetaminophen常用於減緩疼痛與發燒，許多處方與非處方藥均含有此成分。皮膚反應如Stevens-Johnson Syndrome (SJS)、toxic epidermal necrolysis (TEN)，acute generalized exanthematous pustulosis (AGEP)，有可能致命。第一次或任何時候使用acetaminophen皆有可能發生皮膚反應。其他減緩疼痛與發燒的藥品，如非固醇類抗發炎藥也可能造成嚴重皮膚反應，此情形已經紀錄於藥品仿單。

建議

醫療人員須了解acetaminophen有此罕見風險，當評估病人潛在藥物引起皮膚反應時，應考量acetaminophen及其他相關的藥物造成的可能性。當任何病人使用acetaminophen或其他藥物，產生了嚴重皮膚反應，應立即停藥並就醫。當任何人曾有acetaminophen造成嚴重皮膚反應的經驗時，應立即告知醫師，並討論更換其他減緩疼痛發燒的藥品。

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AUDIENCE: Dermatology, Primary Care, Pharmacy

ISSUE: FDA notified healthcare professionals and patients that acetaminophen has been associated with a risk of rare but serious skin reactions. Acetaminophen is a common active ingredient to treat pain and reduce fever; it is included in many prescription and over-the-counter (OTC) products. These skin reactions, known as Stevens-Johnson Syndrome (SJS), toxic epidermal necrolysis (TEN), and acute generalized exanthematous pustulosis (AGEP), can be fatal. These reactions can occur with first-time use of acetaminophen or at any time while it is being taken. Other drugs used to treat fever and pain/body aches (e.g., non-steroidal anti-inflammatory drugs, or NSAIDs, such as ibuprofen and naproxen) also carry the risk of causing serious skin reactions, which is already described in the warnings section of their drug labels.

BACKGROUND: This new information resulted from the Agency's review of the FDA Adverse Event Reporting System (FAERS) database and the medical literature to evaluate cases of serious skin reactions associated with acetaminophen (see Data Summary at link below). It is difficult to determine how frequently serious skin reactions occur with acetaminophen, due to the widespread use of the drug, differences in usage among individuals (e.g., occasional vs. long-term use), and the long period of time that the drug has been on the market; however it is likely that these events (i.e., SJS, TEN, and AGEP) occur rarely.

RECOMMENDATIONS: Health care professionals should be aware of this rare risk and consider acetaminophen, along with other drugs already known to have such an association, when assessing patients with potentially drug-induced skin reactions. Any patient who develops a skin rash or reaction while using acetaminophen or any other pain reliever/fever reducer should stop the drug and seek medical attention right away. Anyone who has experienced a serious skin reaction with acetaminophen should not take the drug again and should contact their health care professional to discuss alternative pain relievers/fever reducers.