

Acetaminophen Toxicity Highlighted in Poster Presentation

A review of published medical literature has found that individuals who receive pain relievers containing acetaminophen (e.g., Tylenol®) are commonly prescribed doses close to or above the U.S. Food and Drug Administration's (FDA) recommended daily maximum dose (4 g per day), putting them at increased risk of acetaminophen overdose and liver toxicity. The research was released in a poster presented at the Academy of Managed Care Pharmacy's annual meeting in Tampa, Florida.

The literature review was performed to provide further insights into patient exposure to high-dose acetaminophen and the risk of overdose and related toxicity in the United States. Acetaminophen can cause liver toxicity (i.e., hepatotoxicity), including serious liver failure, when a patient exceeds the total recommended dosage of less than 4 g per day. The literature review also found:

- Each week, approximately 43 million adults in the United States take some form of acetaminophen.
- The average dose of acetaminophen in the prescriptions for opioid-acetaminophen combination products was 3.7 g ($SD = 34.5$) per day.
- Annually, acetaminophen overdose leads to nearly 80,000 emergency department visits and 30,000 hospitalizations, up to one third of which are unintentionally induced.

Family Photos Transferred to Removable Wallpaper Assist in Comforting LTC Residents

In response to the fact that many long-term care facilities discourage picture frames and placing nails in walls, WeMontage recently launched the world's first online-to-offline photo sharing website (<http://www.wemontage.com>) that transforms memorable photos into removable wallpaper, providing a unique solution for families and their loved ones who have been placed in assisted living facilities.



The WeMontage website allows family members from anywhere in the world to upload pictures that are automatically sorted by size and resolution via an algorithm and output in a removable wallpaper collage. Users can collaborate with each other using the "invite others" feature, a built-in widget that allows multiple people to upload images and collectively create one WeMontage.

A partnership with ScanDigital.com, a company that specializes in turning physical photos into digital files, allows family members to send photos in bulk to be transformed into digital files for WeMontage.

Source. WeMontage. (2014, April 3). Tech Company Launches Effort to Combat Guilt and Depression Associated with Assisted Living and Elderly Care [Press release]. Milwaukee, WI: Author.

Exposure to high doses of acetaminophen, alone or in combination with opioid agents, appears common in the United States, despite the known risks of serious liver damage and death.

"The literature review showed that unintentional overdoses are preventable and may be more likely to lead to acute liver damage than overdoses resulting from intentional self-harm," said Rami Ben-Joseph, PhD, Head of Health Outcomes and Pharma-

coeconomics at Purdue Pharma, which funded the review. "Thus, when prescribing acetaminophen products, physicians should be aware of a patient's overall acetaminophen usage, through both prescription and over-the-counter products containing acetaminophen."

Source. "Research Highlights Risk for Acetaminophen Toxicity from Use of Over the Counter and Prescription Pain Medications." (2014, April 4). Retrieved April 8, 2014, from <http://prn.to/1kGwNmV>.

Emergency Treatment for Opioid Overdose Approved



Kaleo (formerly Intelliject) has announced that the U.S. Food and Drug Administration (FDA) has approved Evzio™ (naloxone hydrochloride injection) for the emergency treatment of known or suspected opioid overdose, as manifested by respiratory and/or central nervous system depression. Evzio is the first and only naloxone auto-injector intended to be available for immediate administration by family members or caregivers for suspected opioid overdose in settings where opioid agents may be present.

Naloxone, the active ingredient in Evzio, has been used for more than 40 years for reversal of respiratory depression due to opioid overdose but has been primarily used by emergency medical services, other medical professionals, and in limited naloxone distribution programs. Evzio will be available to patients and their family members or caregivers via a health care professional's prescription. Evzio should be administered as quickly as possible when an opioid overdose is suspected because prolonged respiratory depression may result in damage to the central nervous system or death. Because people experiencing an opioid overdose generally lose consciousness, in most cases, family members or caregivers will likely be the ones who administer Evzio, which uses voice and visual cues to assist in guiding a user through the injection process.

The New Drug Application for Evzio was granted Fast Track status and received a priority review by the FDA, which are regulatory pathways to accelerate the review and approval of products that fill an unmet medical need. Evzio is expected to be available this summer through all major pharmacies and via mail order with a health care professional's prescription. An assistance program will be available to help patients gain access to the drug.

Source. "U.S. Food and Drug Administration Approves Kaleo's Evzio™ for the Emergency Treatment of Opioid Overdose." (2014, April 3). Retrieved April 8, 2014, from <http://prn.to/1hdqBDB>.

Specifically, there was less atrophy in those patients treated with PBT2 relative to placebo—2.6% and 4.0%, respectively. This is consistent with published measures of atrophy in AD patients versus healthy controls of 4.7% and 1.4%, respectively. Prana is tracking measures of brain volume and cognition in the current 12-month extension study that will be completed at the end of the year. Further analysis of the results is ongoing.

Importantly, PBT2 was shown to be safe and very well tolerated over the 52 weeks. The adverse event profile was equivalent between placebo and treated groups. Forty of the 42 enrolled participants (95%) completed the 52-week treatment period.

Prana is proceeding with its plans toward a confirmatory study for Huntington's disease. Based on Prana's previous discussion with the U.S. Food and Drug Administration, the data on safety and tolerability of PBT2 in AD will support the future clinical development and, ultimately, a New Drug Application in Huntington's disease.

Source. "Prana Biotechnology Announces Preliminary Results of Phase 2 IMAGINE Trial of PBT2 in Alzheimer's Disease." (2014, March 31). Retrieved April 8, 2014, from <http://prn.to/1gImdaG>.

doi:10.3928/00989134-20140430-89

Drug Candidate Does Not Meet Primary Endpoint in Alzheimer's Study

Prana Biotechnology has released topline results of the 12-month Phase II Imaging trial in Alzheimer's Disease ("IMAGINE" Trial), based on draft results.

Prana's drug candidate, PBT2, did not meet its primary endpoint of a statistically significant reduction in the levels of beta-amyloid plaques in the brains of prodromal/mild Alzheimer's disease (AD) patients, as measured using

Pittsburgh compound B-positron emission tomography (PiB-PET) standardized uptake value ratio. Although there was a reduction in the overall levels of the PiB-PET signal in patients treated with PBT2, the results were confounded by an atypical reduction of levels of the PiB-PET signal in the placebo group as well.

No improvement was observed on the secondary endpoints of brain metabolic activity, cognition, and function; however, there was a trend toward preserving hippocampal brain volume in the PBT2 group.

Do You Have Any Product News to Share?

JGN would like to hear about it.

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Journal of Gerontological Nursing

6900 Grove Road, Thorofare, NJ 08086

Fax: (856) 848-6091

E-mail (preferred): jgn@healio.com