



State of Minnesota
The Office of Ombudsman for
Mental Health and Developmental Disabilities
121 7th Place E. Suite 420 Metro Square Building, St. Paul, Minnesota 55101-2117

November 2013

Dear Colleague:

Greetings from the Office of Ombudsman for Mental Health and Disabilities. This cover letter is to announce the [Winter Alerts for 2013/2014](#) from the Medical Review Subcommittee:

2013/2014 Winter Alert

Hypothermia Alert

Frostbite Alert

NWS Wind Chill Chart

If you haven't already, please visit our website to sign up for our List Service for e-mail notification of our Medical Alerts at <https://webmail.mnet.state.mn.us/mailman/listinfo/Medical-alert>

Death and Serious Injury Reporting Update:

Reports of deaths and serious injuries can be faxed or telephoned to the Office of Ombudsman for Mental Health and Developmental Disabilities at the following numbers:

Fax: 651-797-1950

Voice: 651-757-1800

Toll Free: 1-800-657-3506

It has come to our attention that our new fax number only can receive faxes from digital (not analog) fax machines. If you are using an older (analog) fax machine and have difficulty faxing reports to our office, please use our old fax number: 651-296-1021.

This office had hoped to be able to offer on-line reporting of deaths and serious injuries through our website. There has been a delay in that availability. We suggest you ensure that you and your colleagues are members of the List Service (as noted above) for immediate notification when on-line reporting becomes available. We continue to accept reports via fax machine, and we encourage you to use the updated report forms available on our website at <http://mn.gov/omhdd/report-death-or-serious-injury/download/>

MedWatch Updates:

This office continues to recommend that providers, families and clients be aware of the FDA's MedWatch website, which provides updated and on-going information about warnings and alerts for medications and medical devices. Since our Summer Alert, the FDA has released MedWatch Safety Alerts for many medications, many of which are prescribed for clients of this Office. These medications include:

1. Zyprexa Relprevv (Olanzapine Pamoate): Drug Safety Communication - FDA Investigating Two Deaths Following Injection [Posted 06/18/2013]

ISSUE: FDA is investigating two unexplained deaths in patients who received an intramuscular injection of the antipsychotic drug Zyprexa Relprevv (olanzapine pamoate). The patients died 3-4 days after receiving an appropriate

dose of the drug, well after the 3-hour post-injection monitoring period required under the Zyprexa Relprevv Risk Evaluation and Mitigation Strategy (REMS). Both patients were found to have very high olanzapine blood levels after death.

BACKGROUND: Under the REMS, patients are required to receive the Zyprexa Relprevv injection at a REMS-certified health care facility, to be continuously monitored at the facility for at least 3 hours following an injection, and to be accompanied home from the facility. The Zyprexa Relprevv label contains warnings about the risk of post-injection delirium sedation syndrome (PDSS), a serious condition in which the drug enters the blood too fast following an intramuscular injection, causing greatly elevated blood levels with marked sedation (possibly including coma) and/or delirium

RECOMMENDATION: FDA is providing this information to health care professionals while it continues its investigation. If therapy with Zyprexa Relprevv is started or continued in patients, health care professionals should follow the REMS requirements and drug label recommendations. Patients and caregivers should talk to their health care professional(s) about any questions or concerns.

2. Nizoral (ketoconazole): Drug Safety Communication - Potentially Fatal Liver Injury, Risk of Drug Interactions and Adrenal Gland Problems [Posted 07/26/2013]

ISSUE: FDA is taking several actions related to Nizoral (ketoconazole) oral tablets, including limiting the drug's use, warning that it can cause severe liver injuries and adrenal gland problems, and advising that it can lead to harmful drug interactions with other medications. FDA has approved label changes and added a new Medication Guide to address these safety issues. As a result, Nizoral oral tablets should not be a first-line treatment for any fungal infection. Nizoral should be used for the treatment of certain fungal infections, known as endemic mycoses, only when alternative antifungal therapies are not available or tolerated.

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

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.

4. Duragesic (fentanyl) Patches: Drug Safety Communication - Packaging Changes to Minimize Risk of Accidental Exposure [Posted 09/23/2013]

AUDIENCE: Pharmacy, Patient

ISSUE: FDA is requiring color changes to the writing on Duragesic (fentanyl) pain patches so they can be seen more easily. FDA continues to learn of deaths from accidental exposure to fentanyl patches.

Patients and health care professionals are reminded that fentanyl patches are dangerous even after they've been used because they still contain high amounts of strong narcotic pain medicine. Accidental exposure to these patches can cause serious harm and death in children, pets, and others.

In an effort to minimize the risk of accidental exposure to fentanyl patches, FDA is requiring the manufacturer of Duragesic to print the name and strength of the drug on the patch in long-lasting ink, in a color that is clearly visible to patients and caregivers. The current ink color varies by strength and is not always easy to see. This change is intended to enable patients and caregivers to more easily find patches on patients' bodies and see patches that have fallen off, which children or pets could accidentally touch or ingest. The manufacturers of generic fentanyl patches are being requested to make similar changes.

5. Tygacil (tigecycline): Drug Safety Communication - Increased Risk of Death [Posted 09/27/2013]

ISSUE: FDA notified health professionals and their medical care organizations of a new Boxed Warning describing an increased risk of death when intravenous Tygacil is used for FDA-approved uses as well as for non-approved uses. These changes to the Tygacil Prescribing Information are based on an additional analysis that was conducted for FDA-approved uses after FDA issuing a Drug Safety Communication about this safety concern in September 2010.

This analysis showed a higher risk of death among patients receiving Tygacil compared to other antibacterial drugs: 2.5% (66/2640) vs. 1.8% (48/2628), respectively. The adjusted risk difference for death was 0.6% with corresponding 95% confidence interval (0.0%, 1.2%). In general, the deaths resulted from worsening infections, complications of infection, or other underlying medical conditions.

BACKGROUND: Tygacil is FDA-approved to treat complicated skin and skin structure infections (cSSSI), complicated intra-abdominal infections (cIAI), and community-acquired bacterial pneumonia (CABP).

RECOMMENDATION: Health care professionals should reserve Tygacil for use in situations when alternative treatments are not suitable.

Additional information about MedWatch Safety Alerts can be obtained at the FDA's website: <http://www.fda.gov/Safety/MedWatch/SafetyInformation/default.htm>

When administering prescription and over-the-counter medications to your clients, please be aware of the potential side effects of the medications. Document any changes in the client's condition that the medications are intended to treat, as well as any side effects observed and/or reported by your clients, so the prescriber can be informed.

Please call me, at either the toll free or voice numbers, with any questions or concerns. Thank you for your interest in our Medical Alerts and for your continued cooperation with the Office of Ombudsman for Mental Health and Developmental Disabilities.

Sincerely,



Jo Zillhardt, RN-BC, PHN
Medical Review Coordinator

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