

"Giving Voice to Those Seldom Heard"

May 2018

Dear Colleague:

The Medical Review Subcommittee reviews reports of individual deaths and also reviews accumulated data on all deaths and serious injuries reported to our office. Periodically, the MRS develops Medical Alerts based upon its reviews. This cover letter is to announce the Summer Alerts for 2018:

[Summer Alert](#)

[Heat Stroke Alert](#)

[Insect Sting Alert](#)

[Water Safety Alert](#)

For continued updates from the Office of Ombudsman for Mental Health and Developmental Disabilities, you can sign up for the List Service at [Click here to Subscribe or Unsubscribe to the Medical Alerts E-Mail List Service.](#)

When you subscribe to this service, we will notify you by e-mail when we post new Medical Alerts to our website.

All of our Summer Alerts are located here: <https://mn.gov/omhdd/documents/medical-alerts.jsp>

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

Please note the fax number. If your fax report transmission does not appear to be successful when using the preferred fax number (above), please use the back-up fax number: **651-296-1021**.

Thank you for continuing to fax your Serious Injury and Death reports to our Office and for your cooperation with our review process.

MedWatch Safety Alerts - Since the 2017-2018 Winter Alert, the FDA has released MedWatch Safety Alerts for many medications and devices, some of which are prescribed for clients of this Office. These medications and devices include:

Lamictal (lamotrigine): Drug Safety Communication - Serious Immune System Reaction - [Posted 04/25/2018] **ISSUE:** The FDA is warning that the medicine Lamictal (lamotrigine) for seizures and bipolar disorder can cause a rare but very serious reaction that excessively activates the body's infection-fighting immune system. This can cause severe inflammation throughout the body and lead to hospitalization and death, especially if the reaction is not diagnosed and treated quickly. As a result, we are requiring a new warning about this risk be added to the prescribing information in the lamotrigine drug labels.

BACKGROUND: The immune system reaction, called hemophagocytic lymphohistiocytosis (HLH), causes an uncontrolled response by the immune system. HLH typically presents as a persistent fever, usually greater than 101°F, and it can lead to severe problems with blood cells and organs throughout the body such as the liver, kidneys, and lungs.

Lamotrigine is used alone or with other medicines to treat seizures in patients two years and older. It may also be used as maintenance treatment in patients with bipolar disorder to help delay the occurrence of mood episodes such as depression, mania, or hypomania. Stopping lamotrigine without first talking to a prescriber can lead to uncontrolled seizures, or new or worsening mental health problems. Lamotrigine has been approved and on the market for 24 years, and is available under the brand name Lamictal and as generics.

RECOMMENDATION: Healthcare professionals should be aware that prompt recognition and early treatment is important for improving HLH outcomes and decreasing mortality. Diagnosis is often complicated because early signs and symptoms such as fever and rash are not specific. HLH may also be confused with other serious immune-related adverse reactions such as Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS)... For additional information:

<https://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm605628.htm>

Oral Over-the-Counter Benzocaine Products: Drug Safety Communication - Risk of Serious and Potentially Fatal Blood Disorder - ISSUE:

The FDA is warning that over-the-counter (OTC) oral drug products containing benzocaine should not be used to treat infants and children younger than 2 years. We are also warning that benzocaine oral drug products should only be used in adults and children 2 years and older if they contain certain warnings on the drug label. These products carry serious risks and provide little to no benefits for treating oral pain, including sore gums in infants due to teething. Benzocaine, a local anesthetic, can cause a condition in which the amount of oxygen carried through the blood is greatly reduced. This condition, called methemoglobinemia, can be life-threatening and result in death. Due to the significant safety risk of methemoglobinemia, we have urged manufacturers that they should stop marketing OTC oral drug products for treating teething in infants and children younger than 2 years. If companies do not comply, we will take action to remove these products from the market.

We have also urged manufacturers of OTC oral drug products containing benzocaine for adults and children 2 years and older to make the following changes to the labels of their products:

- Adding a warning about methemoglobinemia;
- Adding contraindications, FDA's strongest warnings, directing parents and caregivers not to use the product for teething and not to use in infants and children younger than 2 years; and
- Revising the directions to direct parents and caregivers not to use the product in infants and children younger than 2 years.

BACKGROUND: Benzocaine is a local anesthetic contained in some OTC products for the temporary relief of pain due to minor irritation, soreness, or injury of the mouth and throat. Benzocaine products are marketed as gels, sprays, ointments, solutions, and lozenges under brand names such as Anbesol,

Orabase, Orajel, Baby Orajel, Hurracaine, and Topex, as well as store brands and generics. Prescription local anesthetics include articaine, bupivacaine, chloroprocaine, lidocaine, mepivacaine, prilocaine, ropivacaine, and tetracaine.

RECOMMENDATION: We continue to monitor the safety and effectiveness of OTC benzocaine products and intend to take additional actions in the future as needed. We will notify the public about any updates. In addition to our recent actions regarding OTC benzocaine products, we are also requiring a standardized methemoglobinemia warning to be included in the prescribing information of all prescription local anesthetics. For additional information:

<https://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm608612.htm>

Prescription Opioid Cough and Cold Medicines: Drug Safety Communication - FDA Requires Labeling Changes - ISSUE: FDA is requiring safety labeling changes for prescription cough and cold medicines containing codeine or hydrocodone to limit the use of these products to adults 18 years and older because the risks of these medicines outweigh their benefits in children younger than 18. FDA is also requiring the addition of safety information about the risks of misuse, abuse, addiction, overdose, death, and slowed or difficult breathing to the Boxed Warning, the most prominent warning, of the drug labels for prescription cough and cold medicines containing codeine or hydrocodone.

Some codeine cough medicines are available OTC in a few states, and FDA is also considering regulatory action for these products.

FDA is taking this action after conducting an extensive review and convening a panel of outside experts. Both of these determined the risks of slowed or difficult breathing, misuse, abuse, addiction, overdose, and death with these medicines outweigh their benefits in patients younger than 18.

See the [FDA Drug Safety Communication](#) for a list of prescription cough and cold medicines containing codeine or hydrocodone

BACKGROUND: Codeine and hydrocodone are available in combination with other medicines, such as antihistamines and decongestants, in prescription medicines to treat coughs and symptoms associated with allergies or the common cold. Other non-opioid prescription and OTC medicines are available to treat these symptoms.

RECOMMENDATION: Health care professionals should be aware that FDA is changing the age range for which prescription opioid cough and cold medicines are indicated. These products will no longer be indicated for use in children, and their use in this age group is not recommended. Health care professionals should reassure parents that cough due to a cold or upper respiratory infection is self-limited and generally does not need to be treated. For those children in whom cough treatment is necessary, alternative medicines are available. These include over-the-counter (OTC) products such as dextromethorphan, as well as prescription benzonatate products.

Parents and caregivers should be aware that prescription opioid cough and cold medicines that include codeine or hydrocodone should not be used in children. Codeine and hydrocodone are narcotic medicines called opioids and may carry serious risks when used in children. It is important for parents

and caregivers to understand that a cough due to a common cold often does not need medicines for treatment. If a cough medicine is prescribed, ask your child's health care professional or a pharmacist if it contains an opioid such as codeine or hydrocodone. Always read the labels on prescription bottles. If the medicine prescribed for your child contains an opioid, talk to your child's health care professional about a different, non-opioid medicine, or if you have any questions or concerns. For additional information:

<https://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm592053.htm>

Additional information about MedWatch Safety Alerts can be obtained at the FDA's website:

<https://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm590808.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 health care provider/prescriber can be informed.

Thank you for your interest in our Medical Alerts.

Please call me at 651-431-5202 or 1-800-657-3506 with any questions or concerns.

Sincerely,

Jo Zillhardt, RN-BC, PHN
Medical Review Coordinator

Equal Opportunity Employer