



State of Minnesota

Office of the Ombudsman for Mental Health and Developmental Disabilities

121 7th Place E. Ste 420, Metro Square Bldg., St. Paul, MN 55101-2117
Voice: 651-757-1800 or Toll Free 1-800-657-3506 TTY/Voice MN Relay 711
"Giving voice to those seldom heard"

December 2011

Dear Colleague:

Greetings from the Office of the Ombudsman for Mental Health and Disabilities. This cover letter is to announce the Winter Alerts for 2011/2012 from the Medical Review Subcommittee:

[2011/2012 Winter Alert](#)

[Hypothermia Alert](#)

[Frostbite Alert](#)

[NWS Wind Chill Chart](#)

[New – Medical Alert: Choking Is a Medical Emergency](#)

[New – Medical Alert – Use of over-the-counter medications and possible delay of treatment](#)

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: <http://www.ombudmhdd.state.mn.us/forms/listserve.htm>.

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. During August and September 2011, the FDA has released MedWatch Safety Alerts for many medications, many of which are prescribed for clients of this Office. These medications include the following and many others:

Celexa (citalopram hydrobromide) - Celexa is contraindicated in patients with congenital long QT syndrome (see WARNINGS, PRECAUTIONS, and Drug Interactions).

Saphris (asenapine) Sublingual Tablets - Hypersensitivity reactions, including anaphylaxis and angioedema, have been observed in patients treated with asenapine. In several cases, these reactions occurred after the first dose. These hypersensitivity reactions included: anaphylaxis, angioedema, hypotension, tachycardia, swollen tongue, dyspnea, wheezing and rash.

Actos (pioglitazone hydrochloride) - Urinary Bladder Tumors - Interim results from a study suggested that taking ACTOS longer than 12 months increased the relative risk of developing bladder cancer in any given year by 40% which equates to an absolute increase of 3 cases in 10,000 (from approximately 7 in 10,000 [without ACTOS] to approximately 10 in 10,000 [with ACTOS]).

Ditropan (oxybutynin chloride) tablets - Angioedema of the face, lips, tongue and/or larynx has been reported with oxybutynin. In some cases, angioedema occurred after the first dose. Angioedema associated with upper airway swelling may be life-threatening. If involvement of the tongue, hypopharynx, or larynx occurs, oxybutynin should be promptly discontinued and appropriate therapy and/or measures necessary to ensure a patent airway should be promptly provided.



Neurontin (gabapentin) - Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS), also known as Multiorgan hypersensitivity, has been reported in patients taking antiepileptic drugs, including Neurontin. Some of these events have been fatal or life-threatening. DRESS typically, although not exclusively, presents with fever, rash, and/or lymphadenopathy, in association with other organ system involvement, such as hepatitis, nephritis, hematological abnormalities, myocarditis, or myositis sometimes resembling an acute viral infection. Eosinophilia is often present. Because this disorder is variable in its expression, other organ systems not noted here may be involved. It is important to note that early manifestations of hypersensitivity, such as fever or lymphadenopathy, may be present even though rash is not evident. If such signs or symptoms are present, the patient should be evaluated immediately. Neurontin should be discontinued if an alternative etiology for the signs or symptoms cannot be established.

Zoloft (sertraline hydrochloride) - Co-administration of Zoloft with other drugs which enhance the effects of serotonergic neurotransmission, such as tryptophan, fenfluramine, fentanyl, 5-HT agonists, or the herbal medicine St. John's Wort (*hypericum perforatum*) should be undertaken with caution and avoided whenever possible due to the potential for pharmacodynamic interaction. Laboratory Tests -

False-positive urine immunoassay screening tests for benzodiazepines have been reported in patients taking sertraline. This is due to lack of specificity of the screening tests. False positive test results may be expected for several days following discontinuation of sertraline therapy. Confirmatory tests, such as gas chromatography/mass spectrometry, will distinguish sertraline from benzodiazepines.

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.

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

Sincerely,



Jo Zillhardt, RN-BC, PHN
Medical Review Coordinator

