



Health & Safety Alert #11-03-08

Excessive Psychotropic Medication & Psychotropic Medication Side Effects

It is not unusual for individuals with developmental disabilities to also experience mental illness. The incidence of mental illness among people with mental retardation has been estimated at 30 to 40 percent. The evaluation and treatment of individuals dually-diagnosed with mental retardation and mental illness is the same as for persons without mental retardation. An overview of such evaluation and treatment is provided in the monograph "Clinical Best Practices for Serving People with Developmental Disabilities and Mental Illness," published in a collaborative effort by the Ohio Department of Mental Retardation and Developmental Disabilities, and the Ohio Department of Mental Health. It can be accessed on the Department's Website: <http://odmrdd.state.oh.us>

The treatment of mental illness with medications is termed psychopharmacologic treatment. In choosing treatment we must always recognize the right of a person with mental retardation to receive appropriate care and treatment in the least intrusive manner, and the right to be free from unnecessary chemical or physical restraint.

Medications which are prescribed to improve a person's mental health or their behavior symptoms of mental illness are referred to as psychotropic medications. Anti-depressants, anti-psychotics, mood stabilizers, anti-anxiety agents, sleep agents, stimulants, anti-parkinson and anti-cholinergic agents are such medications. If used for psychotropic purposes, anti-convulsants and cardiac medications are also considered psychotropics.

An individual who is taking psychotropic medications may be unable to adequately verbally express symptoms or medication side effects. Therefore, observation for possible side effects is necessary. Side effects may result from the use of a single medication, or from the interaction of multiple medications. Some side effects are minor, such as the sensation of thirst or increased need for fluids. Side effects such as these can be tolerated when the medication is effective in treating the mental illness while other side effects are more severe. Potential side effects of a specific medication should be provided by the pharmacy.

Many serious side effects are common to most psychotropic medications and include the following:

- A. Allergic reaction (difficulty breathing, swelling of lips/face/tongue, rash or fever).
- B. Change in level of alertness (excess sleepiness, insomnia or confusion).
- C. Eating problems (nausea, vomiting, weight gain or loss).
- D. Change in stool pattern (constipation, diarrhea).
- E. Change in heartbeat (slow, fast, irregular) or blood pressure (high or low).
- F. Fainting or dizziness, especially with change in positions such as upon standing.
- G. Abnormal posture, movements, or gait.
- H. Yellowing of eyes or skin.
- I. Unusual bruising or bleeding.

It is important for staff and families to be well informed about the medications that are needed. The Food and Drug Administration (FDA) has adopted a “black-box” label warning. In the United States, a **black box warning** (also sometimes called a **black label warning**) is a type of warning that appears on the package insert for prescription drugs that may cause serious adverse effects. It is so named for the black border that usually surrounds the text of the warning.

A black box warning means that medical studies indicate that the drug carries a significant risk of serious or even life-threatening adverse effects. The U.S. Food and Drug Administration (FDA) can require a pharmaceutical company to place a black box warning on the labeling of a prescription drug, or in literature describing it. It is the strongest warning that the FDA requires.

“Many of the atypical antipsychotics have the black-box label warning”

Keep in mind that people with heart disease and elderly individuals with dementia have a higher likelihood of serious side effects or sudden death. Some of the antidepressants are contraindicated for these persons.

Below is a list of psychotropic medication commonly used that have a black-box label warning:

- Anafranil
- Asendin
- Aventyl, Pamelor
- Celexa
- Desyrel
- Effexor
- Elavil
- Lexapro
- Ludiomil
- Marplan
- Nardil
- Norpramin, Pertofrane
- Pamate
- Paxil
- Prozac
- Remeron
- Serzone
- Surmontil
- Tofranil
- Vivactil
- Wellbutrin
- Zoloft

What to Do:

- A. Be informed about the black-box warnings and side effects of medication that are being received.
- B. Obtain immediate medical treatment for serious signs and symptoms of possible medication side effects.
- C. Keep the health care provider and guardian informed of any and all side effects.

For questions or comments regarding the above Alert, please contact the MUI/Registry Unit at (614) 995-3810.

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