



Rx Focus

New Anti-psychotic Warnings

The FDA has added warnings to the prescribing information to notify healthcare professionals of patients on atypical antipsychotics. The revision to the WARNINGS section of labeling, describes an increased risk of hyperglycemia and diabetes in patients currently taking atypical antipsychotics. Medications in this therapeutic class include Abilify® (aripiprazole, Bristol Myers Squibb), Cozaryl® (clozapine, manufactured by Novartis and by several generic companies), Geodon® (ziprasidone, Pfizer), Risperdal® (risperidone, Janseen), Seroquel® (quetiapine, AstraZeneca), and Zyprexa® (olanzapine, Lilly).

The warning (attached) makes clear that there is a relationship between antipsychotic use and hyperglycemia-related adverse events.

April Health Observances

Alcohol Awareness Month – sponsored by National Council on Alcoholism and Drug Dependence, www.ncadd.org

Cancer Control Month – sponsored by American Cancer Society, www.cancer.org

Cervical Cancer Screening Month – sponsored by Gynecologic Cancer Foundation, www.wcn.org

Glaucoma Awareness Month – sponsored by Prevent Blindness America, www.preventblindness.org

Thyroid Awareness Month – sponsored by American Association of Clinical Endocrinologist, www.aace.com

National Volunteer Blood Donor Month - sponsored by American Association of Blood Banks, www.aabb.org

WARNINGS

Hyperglycemia and Diabetes Mellitus

Hyperglycemia, in some cases extreme and associated with ketoacidosis or hyperosmolar coma or death, has been reported in patients treated with atypical antipsychotics including Zyprexa. Assessment of the relationship between atypical antipsychotic use and glucose abnormalities is complicated by the possibility of an increased background risk of diabetes mellitus in patients with schizophrenia and the increasing incidence of diabetes mellitus in the general population. Given these confounders, the relationship between atypical antipsychotic use and hyperglycemia-related adverse events is not completely understood. However, epidemiological studies suggest an increased risk of treatment-emergent hyperglycemia-related adverse events in patients treated with the atypical antipsychotics. Precise risk estimates for hyperglycemia related adverse events in patients treated with atypical antipsychotics are not available.

Patients with an established diagnosis of diabetes mellitus who are started on atypical antipsychotics should be monitored regularly for worsening of glucose control. Patients with risk factors for diabetes mellitus (e.g., obesity, family history of diabetes) who are starting treatment with atypical antipsychotics should undergo fasting blood glucose testing at the beginning of treatment and periodically during treatment. Any patient treated with atypical antipsychotics should be monitored for symptoms of hyperglycemia including polydipsia, polyuria, polyphagia, and weakness. Patients who develop symptoms of hyperglycemia during treatment with atypical antipsychotics should undergo fasting blood glucose testing. In some cases, hyperglycemia has resolved when the atypical antipsychotic was discontinued; however, some patients required continuation of anti-diabetic treatment despite discontinuation of the suspect drug.

References:

1. 2004 Safety Alert: Zyprexa (olanzapine), March 1, 2004. <http://www.fda.gov/medwatch/SAFETY/2004/zyprexa.htm>

Updated Antidepressant Warnings

FDA requests warning statement in labeling for certain antidepressants to encourage close observation for worsening depression or the emergence of suicidality.

The FDA asked manufacturers of the following antidepressant drugs to include in their labeling a Warning statement that recommends close observation of adult and pediatric patients for worsening depression or the emergence of suicidality when treated with these agents. The drugs that are the focus of this new warning are: Prozac (fluoxetine); Zoloft (sertraline); Paxil (paroxetine); Luvox (fluvoxamine); Celexa (citalopram); Lexapro (escitalopram); Wellbutrin (bupropion); Effexor (venlafaxine); Serzone (nefazodone); and Remeron (mirtazapine).

References:

1. FDA Public Health Advisory, March 22, 2004. <http://www.fda.gov/cder/drug/antidepressants/AntidepressantPHA.htm>



New Drug Approvals

Sensipar™

Approved 3/8/2004

Chemical Name: Cinacalcet

Manufacturer: Amgen

Therapeutic Class: Parathyroid Calcium Enhancer

Approved Indications: Treatment hyperparathyroidism associated with renal failure and in patients with parathyroid cancer.

Other Drugs in Class: First medication in therapeutic class

Caduet™

Approved 1/30/2004

Chemical Name: Amlodipine/Atorvastatin

Manufacturer: Pfizer

Therapeutic Class: Hypertension/elevated cholesterol

Approved Indications: Indicated in patients for whom treatment with both amlodipine and atorvastatin is appropriate.

Other Drugs in Class: These medications are available separately as Norvasc® and Lipitor®. There are no other combination products currently available.

Estrogel™

Approved 2/9/2004

Chemical Name: Estradiol

Manufacturer: Solvay Pharmaceuticals

Therapeutic Class: Estrogen hormone preparations

Approved Indications: Treatment of moderate to severe vasomotor symptoms associated with menopause, and treatment of moderate to severe symptoms of vulvar and vaginal atrophy associated with the menopause.

Other Drugs in Class: Oral, injectable and transdermal patches containing Estradiol.



New Generic Approvals

Quinaretic Tablets (quinapril hydrochloride and hydrochlorothiazide tablets)

Approved 3/31/2004

Brand Name Equivalent: Accuretic®

Manufacturer: Amide Pharmaceuticals

Therapeutic Class: Combination ACE Inhibitor-Diuretic

Approved Indication: Hypertension, Congestive Heart Failure.

Oxycodone HCl Extended-Release

Approved: 3/24/2004

Brand Name Equivalent: Oxycontin®

Manufacturer: Endo Pharmaceuticals Holdings Inc. (10mg, 20mg, 40mg) & Teva Pharmaceuticals USA (80mg)

Therapeutic Class: Narcotic Analgesic

Approved Indication: Management of moderate to severe pain

Nitrofurantoin Mono/Mac 100mg

Approved: 3/29/2004

Brand Name Equivalent: Macrobid®

Manufacturer: Mylan Laboratories Inc.

Therapeutic Class: Urinary Antibacterials

Approved Indication: Treatment of acute uncomplicated urinary tract infections (acute cystitis) caused by susceptible strains of Escherichia coli or Staphylococcus saprophyticus.

Bupropion Sustained-Release

Approved 3/23/2004

Brand Name Equivalent: Wellbutrin® SR 150mg

Manufacturer: Teva Pharmaceuticals USA

Therapeutic Class: Norepinephrine and Dopamine

Reuptake Inhibitor

Approved Indication: Depression

Desferoxamine Mesylate Injection

Approved 3/17/2004

Brand Name Equivalent: Desferal®

Manufacturer: Abbott Hospital

Therapeutic Class: Agents to Treat Metallic Poisoning

Approved Indication: Treatment of acute iron intoxication or chronic iron overload.



675 Foxon Road, Suite 204
East Haven CT 06513
Phone: (800) 936-1193
Fax: (203) 468-8416