

FYI

Opioid Addiction Treatment

Three free booklets on medication-assisted treatment for opioid addiction are available from the Substance Abuse and Mental Health Services Administration. The booklets have information on medication options, proper use of medications, common side effects, and the process of recovery. “The Facts About Naltrexone for Treatment of Opioid Addiction,” “The Facts About Buprenorphine for Treatment of Opioid Addiction,” and “Medication Assisted Treatment for Opioid Addiction: Facts for Families and Friends,” can be ordered at <http://ncadistore.samhsa.gov>.

Coping With Medical Debt

Families USA is offering a free, downloadable consumer guide, “Your Medical Bills: A Consumer’s Guide to Coping With Medical Debt,” which provides step-by-step guidance to people who are overwhelmed by medical bills. To download the guide, visit the Families USA Web site at www.familiesusa.org/assets/pdfs/medical-debt-guide.pdf.

\$39 Million in Grants Awarded

The Substance Abuse and Mental Health Services Administration has awarded grants totaling \$39 million over the next 3 years to help 26 Community Treatment and Services Centers nationwide meet the special needs of children who suffer from or are at risk for traumatic stress. For more information, visit www.samhsa.gov/Grants.

Grants Awarded to Drug Courts

The Substance Abuse and Mental Health Services Administration has awarded more than \$38.2 million over 3 years to expand the services of 44 adult drug courts nationwide. These special dockets focus on those who are in the criminal justice system largely because of underlying substance abuse problems. For more information, visit www.samhsa.gov/Grants.

SAMHSA Grants Awarded

The Substance Abuse and Mental Health Services Administration has awarded six grants totaling about \$1.2 million over 3 years to state-based organizations in Ohio, West Virginia, Arkansas, Oregon, Illinois, and North Dakota that serve children and adolescents with serious emotional disturbances. For more information, visit www.samhsa.gov.

Drug Coverage for Unemployed

Pfizer Inc. is offering the “Maintain” program to help eligible, newly unemployed Americans without prescription coverage who are in financial need continue to get their Pfizer medications free of charge for up to 12 months or until they become insured, whichever comes first. For more information, visit Pfizer Inc. at www.PfizerHelpfulanswers.com.

Suicide Prevention

The U.S. Substance Abuse and Mental Health Services Administration is offering a new manual, “Addressing Suicidal Thoughts and Behaviors in Substance Abuse Treatment,” which is No. 50 in its Treatment Improvement Protocol (TIP) series. This free manual is available online at <http://www.ncbi.nlm.nih.gov/books/bv.fcgi?rid=hstat5.chapter.93877>.

TIP for Substance Abuse Tx

The free, three-part Treatment Improvement Protocol (TIP) No. 52, “Clinical Supervision and Professional Development of the Substance Abuse Counselor,” is now available. For more information, contact the Substance Abuse and Mental Health Services Administration at enet-work@samhsa.hhs.gov.

New Anti-Meth Campaign

The U.S. Office of National Drug Control Policy is launching a new Anti-Meth Campaign for young adults. A downloadable handbook and customizable public service announcements are available for free. For more information, visit the ONDCP Web site at <http://www.methresources.gov/index.html>.

NIA Fact Sheet on Smell and Taste

The National Institute on Aging is offering a fact sheet titled “Smell and Taste: Spice of Life.” It describes the importance of smell and taste, possible causes of change in these senses and ways to deal with them, and tips for eating a healthful diet when changes in taste occur during cancer therapy. To download or order free copies, visit www.nia.nih.gov/HealthInformation/Publications/smell.htm.

Resources for LGBT Seniors

The U.S. Department of Health and Human Services is creating the first national resource center to help communities provide services to older lesbian, gay, bisexual, and transgender people. For more information, visit the Administration on Aging’s Web site at www.aoa.gov/AoARoot/Grants/Funding/index.aspx.

INDEX OF ADVERTISERS

American Professional Agency, Inc.	
Insurance	9
Forest Laboratories, Inc.	
Namenda	20a-20b
Lexapro	37-41
Mylan Pharmaceuticals Inc.	
Paroxetine Hydrochloride	23-26
Ortho-McNeil-Janssen Pharmaceuticals, Inc.	
INVEGA	14-18
INVEGA SUSTENNA	30-34
Risperdal CONSTA	53-56
Pfizer Inc.	
Pristiq	11-12
Geodon	44a-44b
Shire US Inc.	
Corporate	5
Intuniv	7-8, 28a-28d
Vyvanse	47-48
University of Pittsburgh Medical Center	
Corporate	43

RISPERDAL® CONSTA®
(risperidone) LONG-ACTING INJECTION

Brief Summary

BEFORE PRESCRIBING RISPERDAL® CONSTA®, PLEASE SEE FULL PRESCRIBING INFORMATION, INCLUDING BOXED WARNING.

WARNING: INCREASED MORTALITY IN ELDERLY PATIENTS WITH DEMENTIA-RELATED PSYCHOSIS

Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. Analyses of 17 placebo-controlled trials (modal duration of 10 weeks), largely in patients taking atypical antipsychotic drugs, revealed a risk of death in drug-treated patients of between 1.6 to 1.7 times the risk of death in placebo-treated patients. Over the course of a typical 10-week controlled trial, the rate of death in drug-treated patients was about 4.5%, compared to a rate of about 2.6% in the placebo group. Although the causes of death were varied, most of the deaths appeared to be either cardiovascular (e.g., heart failure, sudden death) or infectious (e.g., pneumonia) in nature. Observational studies suggest that, similar to atypical antipsychotic drugs, treatment with conventional antipsychotic drugs may increase mortality. The extent to which the findings of increased mortality in observational studies may be attributed to the antipsychotic drug as opposed to some characteristic(s) of the patients is not clear. **RISPERDAL® CONSTA® (risperidone) is not approved for the treatment of patients with dementia-related psychosis. [See Warnings and Precautions]**

RISPERDAL® CONSTA® is indicated as monotherapy or as adjunctive therapy to lithium or valproate for the maintenance treatment of Bipolar I Disorder [see Clinical Studies (14.2, 14.3) in full PI].

CONTRAINDICATIONS: RISPERDAL® CONSTA® (risperidone) is contraindicated in patients with a known hypersensitivity to the product.

WARNINGS AND PRECAUTIONS: Increased Mortality in Elderly Patients with Dementia-Related Psychosis

Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. **RISPERDAL® CONSTA® (risperidone) is not approved for the treatment of dementia-related psychosis (see Boxed Warning).**

Cerebrovascular Adverse Events, Including Stroke, in Elderly Patients with Dementia-Related Psychosis:

Cerebrovascular adverse events (e.g., stroke, transient ischemic attack), including fatalities, were reported in patients (mean age 85 years; range 73-97) in trials of oral risperidone in elderly patients with dementia-related psychosis. In placebo-controlled trials, there was a significantly higher incidence of cerebrovascular adverse events in patients treated with oral risperidone compared to patients treated with placebo. RISPERDAL® CONSTA® is not approved for the treatment of patients with dementia-related psychosis [See also Boxed Warning and Warnings and Precautions]. **Neuroleptic Malignant Syndrome (NMS):** A potentially fatal symptom complex sometimes referred to as Neuroleptic Malignant Syndrome (NMS) has been reported in association with antipsychotic drugs. Clinical manifestations of NMS are hyperpyrexia, muscle rigidity, altered mental status, and evidence of autonomic instability (irregular pulse or blood pressure, tachycardia, diaphoresis, and cardiac dysrhythmia). Additional signs may include elevated creatine phosphokinase, myoglobinuria (rhabdomyolysis), and acute renal failure. The diagnostic evaluation of patients with this syndrome is complicated. In arriving at a diagnosis, it is important to identify cases in which the clinical presentation includes both serious medical illness (e.g., pneumonia, systemic infection, etc.) and untreated or inadequately treated extrapyramidal signs and symptoms (EPS). Other important considerations in the differential diagnosis include central anticholinergic toxicity, heat stroke, drug fever, and primary central nervous system pathology. The management of NMS should include: (1) immediate discontinuation of antipsychotic drugs and other drugs not essential to concurrent therapy; (2) intensive symptomatic treatment and medical monitoring; and (3) treatment of any concomitant serious medical problems for which specific treatments are available. There is no general agreement about specific pharmacological treatment regimens for uncomplicated NMS. If a patient requires antipsychotic drug treatment after recovery from NMS, the potential reintroduction of drug therapy should be carefully considered. The patient should be carefully monitored, since recurrences of NMS have been reported. **Tardive Dyskinesia:** A syndrome of potentially irreversible, involuntary, dyskinetic movements may develop in patients treated with antipsychotic drugs. Although the prevalence of the syndrome appears to be highest among the elderly, especially elderly women, it is impossible to rely upon prevalence estimates to predict, at the inception of antipsychotic treatment, which patients are likely to develop the syndrome. Whether antipsychotic drug products differ in their potential to cause tardive dyskinesia is unknown. The risk of developing tardive dyskinesia and the likelihood that it will become irreversible are believed to increase as the duration of treatment and the total cumulative dose of antipsychotic drugs administered to the patient increase. However, the syndrome can develop, although much less commonly, after relatively brief treatment periods at low doses. There is no known treatment for established cases of tardive dyskinesia, although the syndrome may remit, partially or completely, if antipsychotic treatment is withdrawn. Antipsychotic treatment, itself, however, may suppress (or partially suppress) the signs and symptoms of the syndrome and thereby may possibly mask the underlying process. The effect that symptomatic suppression has upon the long-term course of the syndrome is unknown. Given these considerations, RISPERDAL® CONSTA® should be prescribed in a manner that is most likely to minimize the occurrence of tardive dyskinesia. Chronic antipsychotic treatment should generally be reserved for patients who suffer from a chronic illness that: (1) is known to respond to antipsychotic drugs, and (2) for whom alternative, equally effective, but potentially less harmful treatments are not available or appropriate. In patients who do require chronic treatment, the smallest dose and the shortest duration of treatment producing a satisfactory clinical response should be sought. The need for continued treatment should be reassessed periodically. If signs and symptoms of tardive dyskinesia appear in a patient treated with RISPERDAL® CONSTA®, drug discontinuation should be considered. However, some patients may require treatment with RISPERDAL® CONSTA® despite the presence of the syndrome. **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 RISPERDAL®. 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. **Hyperprolactinemia:** As with other drugs that antagonize dopamine D₂ receptors, risperidone elevates prolactin levels and the elevation persists during chronic administration. Risperidone is associated with higher levels of prolactin elevation than other antipsychotic agents. Hyperprolactinemia may suppress hypothalamic GnRH, resulting in reduced pituitary gonadotropin secretion. This, in turn, may inhibit reproductive function by impairing gonadal steroidogenesis in both female and male patients. Galactorrhea, amenorrhea, gynecomastia, and impotence have been reported in patients receiving prolactin-elevating compounds. Long-standing hyperprolactinemia when associated with hypogonadism may lead to decreased bone density in both female and male subjects. Tissue culture experiments indicate that approximately one-third of human breast cancers are prolactin dependent *in vitro*, a factor of potential importance if the prescription of these drugs is contemplated in a patient with previously detected breast cancer. An increase in pituitary gland, mammary gland, and pancreatic