



FDA Issues Approvable Letter for RISPERDAL(R) to Treat Adolescents with Schizophrenia and Children and Adolescents with Bipolar Mania

TITUSVILLE, N.J., June 21, 2007 /PRNewswire via COMTEX News Network/ -- Johnson & Johnson Pharmaceutical Research & Development, L.L.C. (J&JPRD) announced it has received an approvable letter from the U.S. Food and Drug Administration (FDA) regarding two supplemental New Drug Applications (sNDA) for RISPERDAL(R) (risperidone), filed on Dec. 21, 2006. The sNDAs are for the treatment of schizophrenia in adolescents ages 13-17 years and for the short-term treatment of bipolar mania associated with bipolar I disorder in children and adolescents ages 10-17 years, respectively. The FDA has not asked for any additional studies. J&JPRD is currently reviewing the approvable letter and looks forward to finalizing the label with the agency.

Important Safety Information For RISPERDAL(R)

Elderly Patients with dementia-related psychosis treated with atypical antipsychotic drugs are at an increased risk of death compared to placebo. RISPERDAL(R) (risperidone) is not approved for the treatment of patients with Dementia-Related Psychosis.

Schizophrenia: The most common side effects that occurred with RISPERDAL(R) were anxiety, sleepiness, restlessness, tremors and muscle stiffness; dizziness, constipation, nausea, indigestion, runny nose, rash and rapid heartbeat.

Bipolar Mania: The most common side effects that occurred in clinical trials with RISPERDAL(R), in the treatment of bipolar mania either alone or in combination with a mood stabilizer (lithium or valproate) were: sleepiness, muscle stiffness, restlessness, tremor, indigestion, nausea, abnormal vision, muscle aches, dizziness, runny nose, diarrhea, increased saliva, stomach pain and urinary incontinence.

Autistic Disorder: The most common side effects that occurred with RISPERDAL(R) were sleepiness, increased appetite, fatigue, upper respiratory tract infection, increased saliva, constipation, dry mouth, tremor, muscle stiffness, dizziness, repetitive behavior, involuntary movement, rapid heartbeats, confusion, weight increase.

A rare but serious side effect that has been reported with this kind of medicine, including RISPERDAL(R), is known as neuroleptic malignant syndrome (NMS). NMS is characterized by muscle rigidity, fever and can be serious.

You may have heard the term "tardive dyskinesia." These are usually persistent, uncontrollable, slow or jerky facial or body movements that can be caused by all medications of this type. If you have these symptoms, talk to your health care professional.

Studies suggest an increased risk of elevated blood sugar-related side effects, and sometimes potentially fatal, in patients treated with this class of medications, including RISPERDAL(R). Some people may need regular blood sugar testing.

Some people taking RISPERDAL(R) may feel faint or lightheaded when they stand up or sit up too quickly. By standing up or sitting up slowly and following your health care professional's dosing instructions, this side effect may be reduced or it may go away over time.

You may have heard the term "extrapyramidal symptoms" (EPS). These are usually persistent movement disorders or muscle disturbances, such as restlessness, tremors and muscle stiffness. Some people taking RISPERDAL(R) have these side effects. If you have these symptoms, talk to your health care professional.

Some medications may interact with RISPERDAL(R). Avoid alcohol while on RISPERDAL(R).

Inform your health care professional if you are pregnant or if you are planning to get pregnant while taking RISPERDAL(R). Do not breastfeed if you are taking RISPERDAL(R).

RISPERDAL(R) may affect your driving ability, therefore, do not drive or operate machines before talking to your health care professional.

RISPERDAL(R) may affect alertness and motor skills; use caution until the effect of RISPERDAL(R) is known.

Please see full important U.S. prescribing information for RISPERDAL(R) at www.janssen.com.

Janssen, L.P., based in Titusville, NJ, is the only pharmaceutical company in the U.S. dedicated solely to mental health. The company currently markets prescription medications for the treatment of schizophrenia, bipolar mania and irritability associated with autistic disorder. For more information about Janssen, L.P., visit www.janssen.com, and for more information on RISPERDAL(R), visit www.RISPERDAL.com.

Johnson & Johnson Pharmaceutical Research and Development, L.L.C., is headquartered in Raritan, NJ, and has facilities throughout Europe and the U.S. The company is leveraging drug discovery and drug development in a variety of therapeutic areas to address unmet medical needs worldwide.

SOURCE Johnson & Johnson Pharmaceutical Research and Development, L.L.C.

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