



FOR IMMEDIATE RELEASE

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Ortho-McNeil-Janssen Pharmaceuticals, Inc. Voluntarily Recalls One Lot of RISPERDAL[®] Tablets and One Lot of Risperidone Tablets

Titusville, N.J., June 17, 2011 – Ortho-McNeil-Janssen Pharmaceuticals, Inc. is initiating a voluntary recall of one lot of RISPERDAL[®] (risperidone) 3mg Tablets, marketed by Janssen Division of Ortho-McNeil-Janssen Pharmaceuticals, Inc. and one lot of risperidone 2mg Tablets, marketed by Patriot Pharmaceuticals, LLC, a wholly owned subsidiary of Ortho-McNeil-Janssen Pharmaceuticals, Inc. The recalls stem from two consumer reports of an uncharacteristic odor thought to be caused by trace amounts of TBA (2,4,6 tribromoanisole).

TBA is a byproduct of a chemical preservative sometimes applied to wood often used in the construction of pallets on which materials are transported and stored. In January 2010, the company instituted a number of actions to reduce the potential of TBA contamination, including requiring suppliers to certify that they do not use pallets made from chemically-treated wood.

While not considered to be toxic, TBA can generate an offensive odor and a very small number of patients have reported temporary gastrointestinal symptoms when taking other products with this odor. As it relates to RISPERDAL[®] and risperidone, there have been no reported serious adverse events caused by the presence of TBA.

The RISPERDAL[®] lot – which includes approximately 16,000 bottles – was shipped between 8/27/2010 and 2/15/2011. The company believes there are approximately 1,600 bottles of RISPERDAL[®] from this lot remaining in the marketplace. The risperidone lot – which includes approximately 24,000 bottles – was shipped between 11/10/2010 and 1/01/2011. The company believes there are fewer than 1,200 bottles of risperidone from this lot remaining in the marketplace.

Package Description	NDC Code	Lot Number	Expiry
RISPERDAL [®] (risperidone) Tablets 3mg Bottles of 60 Tablets	50458-330-06	0GG904	May 2012
Risperidone Tablets 2mg Bottles of 60 Tablets	50458-593-60	OIG175	August 2012



RISPERDAL[®] (risperidone) is used for the treatment of schizophrenia in adults and adolescents ages 13-17 years.

RISPERDAL[®] (risperidone) is used alone or in combination with other medicines (valproate or lithium) in adults for the short-term treatment of bipolar mania; or alone in adults, children and adolescents ages 10-17 years for the short-term treatment of bipolar mania.

RISPERDAL[®] (risperidone) is used for the treatment of irritability associated with autistic disorder in children and adolescents ages 5-16 years.

Ortho-McNeil-Janssen Pharmaceuticals, Inc. has initiated these recalls in the U.S. and Puerto Rico at the wholesale and retail (pharmacy) level and is communicating this information to these customers. The company does not anticipate a product shortage resulting from this action.

Patients should not stop taking their medication. Anyone experiencing an uncharacteristic odor associated with RISPERDAL[®] 3mg Tablets or risperidone 2mg Tablets should return the tablets to their pharmacist, and contact their healthcare professional if they have questions. Patients or healthcare professionals can contact the Medical Information Recall Line at 1-800-634-8977 (Monday – Friday, 9 am – 5 pm ET). Information can also be found on www.risperdal.com and www.patriotpharmaceuticals.com

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program online, or through regular mail or by fax.

- Online: www.fda.gov/medwatch/report.htm
- Regular Mail: Use postage-paid, pre-addressed Form FDA 3500 available at: www.fda.gov/medwatch/getforms.htm. Mail to address on the pre-addressed form.
- Fax: 1.800.FDA.0178

We conducted an investigation involving our suppliers to evaluate the potential source of this TBA issue. This investigation revealed that some of the wooden pallets used by one of our suppliers in its warehouse were contaminated with TBA. In addition, some of the packaging components manufactured by our supplier were exposed to these pallets. We have initiated a deeper investigation to determine the potential impact of these findings to other products. We also are working with peer companies to better understand how and where TBA is entering and impacting our supply chains and what we can do to further mitigate this exposure.



The voluntary recall, being implemented with the knowledge of the U.S. Food and Drug Administration (FDA), was initiated after enhanced surveillance and complaint monitoring programs escalated two odor-related reports.

RISPERDAL® 3mg Tablets are yellow and imprinted with “JANSSEN” on one side and R3 on the other. Risperidone 2mg Tablets are orange and imprinted “PATR” on one side and R2 on the other.

About Ortho-McNeil-Janssen Pharmaceuticals, Inc.

Ortho-McNeil-Janssen Pharmaceuticals, Inc. (OMJPI) provides medicines for an array of health concerns, including central nervous system disorders, such as schizophrenia and epilepsy; women's health; urology; gastrointestinal conditions; and infectious diseases. The company strives to provide innovative, high quality, safe and effective treatments and continually seeks new opportunities to offer solutions for unmet health care needs. Ortho-McNeil-Janssen Pharmaceuticals, Inc. is headquartered in Titusville, New Jersey.

About Janssen

Janssen Division of Ortho-McNeil-Janssen Pharmaceuticals, Inc., is based in Titusville, New Jersey, and is the only large pharmaceutical company in the United States dedicated solely to mental health. Janssen currently markets prescription medications for the treatment of schizophrenia, Bipolar 1 Disorder, and schizoaffective disorder. Ortho-McNeil-Janssen Pharmaceuticals, Inc., is a member of the Johnson & Johnson Family of Companies. For more information about Janssen, visit <http://www.janssen.com>.

About Patriot Pharmaceuticals, LLC

Patriot Pharmaceuticals, LLC is a wholly owned subsidiary of Ortho-McNeil-Janssen Pharmaceuticals, Inc. The company markets and distributes authorized generic pharmaceuticals, including itraconazole, ketoconazole, galantamine, Tramadol HCl ER 100mg and 200mg and risperidone. Patriot is located in Horsham, PA.

Important Safety Information About RISPERDAL® and Risperidone

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

The most common adverse reactions observed in all clinical trials with RISPERDAL® occurring at a rate of at least 10% were drowsiness, increased appetite, fatigue,

insomnia, sedation, tremor, muscle stiffness, vomiting, coughing, constipation, stuffy nose, runny nose, drooling, dry mouth, abdominal pain, dizziness, nausea, anxiety, headache, nasal congestion, common cold, rash, and restlessness.

Neuroleptic Malignant Syndrome (NMS) is a rare and potentially fatal side effect reported with RISPERDAL® and similar medicines. Call your doctor immediately if the person being treated develops symptoms such as high fever; stiff muscles; shaking; confusion; sweating; changes in pulse, heart rate, or blood pressure; or muscle pain and weakness. Treatment should be stopped if the person being treated has NMS.

Tardive Dyskinesia (TD) is a serious, sometimes permanent side effect reported with RISPERDAL® and similar medications. TD includes uncontrollable movements of the face, tongue, and other parts of the body. The risk of developing TD and the chance that it will become permanent is thought to increase with the length of therapy and the overall dose taken by the patient. This condition can develop after a brief period of therapy at low doses, although this is much less common. There is no known treatment for TD, but it may go away partially or completely if therapy is stopped.

RISPERDAL® and similar medications can raise the blood levels of a hormone known as prolactin, causing a condition known as hyperprolactinemia. Blood levels of prolactin remain elevated with continued use. Some side effects seen with these medications include the absence of a menstrual period; breasts producing milk; the development of breasts by males; and the inability to achieve an erection. The connection between prolactin levels and side effects is unknown.

High blood sugar and diabetes have been reported with RISPERDAL® and similar medications. If the person being treated has diabetes or risk factors such as being overweight or a family history of diabetes, blood sugar testing should be performed at the beginning and throughout treatment. Complications of diabetes can be serious and even life threatening. If signs of high blood sugar or diabetes develop, such as being thirsty all the time, going to the bathroom a lot, or feeling weak or hungry, contact your doctor.

RISPERDAL® should be used cautiously in people with a seizure disorder, who have had seizures in the past, or who have conditions that increase their risk for seizures.

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

Extrapyramidal Symptoms (EPS) are usually persistent movement disorders or muscle disturbances, such as restlessness, tremors, and muscle stiffness. If you observe any of these symptoms, talk to your healthcare professional.



Some medications interact with RISPERDAL[®]. Please inform your healthcare professional of any medications or supplements that you are taking. Avoid alcohol while taking RISPERDAL[®].

Inform your healthcare professional if you are pregnant or if you are planning to get pregnant while taking RISPERDAL[®]. Do not breast-feed if you are taking RISPERDAL[®].

RISPERDAL[®] may affect your driving ability; therefore, do not drive or operate machinery before talking to your healthcare professional.

RISPERDAL[®] may affect alertness and motor skills; use caution until the effect of RISPERDAL is known.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995. These statements are based on current expectations of future events. If underlying assumptions prove inaccurate or unknown risks or uncertainties materialize, actual results could vary materially from the expectations and projections of Ortho-McNeil-Janssen Pharmaceuticals, Inc. and/or Johnson & Johnson. Risks and uncertainties include, but are not limited to, general industry conditions and competition; economic factors, such as interest rate and currency exchange rate fluctuations; technological advances and patents attained by competitors; challenges inherent in new product development, including obtaining regulatory approvals; domestic and foreign health care reforms and governmental laws and regulations; trends toward health care cost containment; and increased scrutiny of the healthcare industry by government agencies. A further list and description of these risks, uncertainties and other factors can be found in Exhibit 99 of Johnson & Johnson's Annual Report on Form 10-K for the fiscal year ended January 2, 2011. Copies of this Form 10-K, as well as subsequent filings, are available online at www.sec.gov, www.jnj.com or on request from Johnson & Johnson. Neither Ortho-McNeil-Janssen Pharmaceuticals, Inc. nor Johnson & Johnson undertake to update any forward-looking statements as a result of new information or future events or developments.

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