

# Rx Update Safety Alert

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**FUTURE  
SCRIPTS**  
A Catalyst Rx Company



## What You Need to Know

- Risperdal (risperidone) 3mg tablets [lot # 0GG904] and risperidone 2mg tablets [lot # OIG175] have been recalled due to an uncharacteristic odor.
- Risperidone is used for the treatment of schizophrenia, bipolar mania and irritability associated with autistic disorder.
- The recalled lots are packaged in 60-count bottles. The 3mg bottle expires May 2012 and the 2mg bottle expires August 2012.
- Patients should return the recalled products to the location from which it was obtained.

## Risperdal (risperidone) Voluntary Recall

### **Issue:**

On June 17, 2011, the U.S. Food and Drug Administration (FDA) and Ortho-McNeil-Janssen Pharmaceuticals, Inc. announced a voluntary recall of one lot of Risperdal (risperidone) 3mg tablets and one lot of risperidone 2mg tablets.

### **Background:**

This voluntary recall was initiated due to consumer reports of a musty odor. The uncharacteristic odor is thought to be caused by trace amounts of TBA (2,4,6 tribromoanisole). While not toxic, TBA can generate an offensive odor and a small number of patients have reported temporary gastrointestinal symptoms. There have been no reported serious adverse events caused by the presence of TBA in these medications.

### **Product-Specific Information:**

Risperidone is used for the treatment of schizophrenia, bipolar mania and irritability associated with autistic disorder. The recalled products were distributed to wholesalers and pharmacies nationwide. This recall is a precautionary measure and the affected products are listed in the table below:

Product	Package Size	NDC Number	Lot Number	Expiration Date
Risperdal (risperidone) 3mg tablets	60-count	50458-330-06	0GG904	May 2012
risperidone 2mg tablets	60-count	50458-593-60	OIG175	August 2012

### **Recommendation:**

Patients in possession of a recalled product are encouraged to:

- Immediately return it to the location from which it was obtained (e.g., doctor's office, pharmacy, etc.).
- Contact their healthcare provider to discuss any concerns.
- Report any adverse effects associated with the use of the recalled product to the FDA's *MedWatch* program at [www.fda.gov/MedWatch/report.htm](http://www.fda.gov/MedWatch/report.htm).

FutureScripts will continue to monitor this situation and will provide additional updates as appropriate.

### **Source:**

[www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm259901.htm](http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm259901.htm)

*Brand-names are the property of their respective manufacturers.*