Drugs

FDA Drug Safety Communication: Medication errors resulting from confusion between risperidone (Risperdal) and ropinirole (Requip)

Safety Announcement
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Safety Announcement

[06-13-2011] The U.S. Food and Drug Administration (FDA) is alerting the public to medication error reports in which patients were given risperidone (Risperdal) instead of ropinirole (Requip) and vice versa. In some cases, patients who took the wrong medication needed to be hospitalized.

The FDA determined that the factors contributing to the confusion between the two products include:

1. Similarities of both the brand (proprietary) and generic (established) names
2. Similarities of the container labels and carton packaging
3. Illegible handwriting on prescriptions
4. Overlapping product characteristics, such as the drug strengths, dosage forms, and dosing intervals.

Patients who take Requip, Risperdal, or their generic equivalents are reminded to take note of the name and appearance of their medication, know why they are taking it, and to ask questions when the medication appears different than what they expect.

Healthcare Professionals are reminded to clearly print or spell out the medication name on prescriptions and make certain their patients know the name of their prescribed medication and their reason for taking it.

FDA is requesting the manufacturers of Requip (GlaxoSmithKline), Risperdal (Johnson & Johnson), and the generic ropinirole and risperidone products to take the following measures to reduce the potential for confusion between the two products:

- Use of "tall man" lettering on container labels and carton packaging to present the generic names as risperiDONE and rOPINIRole, which may improve the ability of healthcare professionals to distinguish between the two drug names.
- Change individual labels and carton packaging to provide better visual differentiation between the generic products for risperidone and ropinirole in order to reduce the potential for confusion. Currently, the label and packaging features (i.e., similar font size and type, layout, and color) for generic ropinirole and risperidone products make the bottles look similar (See Table 1 below).

Additional Information for Patients

- Check the name of the medication and the appearance of the tablets in the prescription bottle to confirm the medication you receive is what you expect. If something looks different, talk to your pharmacist, and ask to see the original bottle from which the medication was filled.

Facts about Risperidone and Ropinirole

- Risperidone (Risperdal) is an antipsychotic medication used to treat mental illnesses including schizophrenia, bipolar disorder, and irritability associated with autistic disorder.
- Ropinirole (Requip) is a dopamine agonist used in the treatment of Parkinson’s disease and Restless Legs Syndrome.

Additional Information for Patients

Check the name of the medication and the appearance of the tablets in the prescription bottle to confirm the medication you receive is what you expect. If something looks different, talk to your pharmacist, and ask to see the original bottle from which the medication was filled.
Ask your pharmacist to confirm the purpose of the medication. Ask additional questions if the purpose is different from what your healthcare professional told you.

Report any side effects or medication errors you experience to the FDA MedWatch program using the information in the "Contact Us" box at the bottom of the page.

**Additional Information for Healthcare Professionals**

- Be sure to clearly print the drug name on written prescriptions.
- Be sure to spell out the drug name when prescribing over the telephone.
- Counsel patients about their prescribed medication, making sure the patient understands its purpose. Including the medical reason for the medication on the prescription may help ensure the patient gets the correct medication.
- Pharmacists are advised to physically separate the stocks of these two drugs on the shelf or wherever they are stored.
- Pharmacists are advised to confirm the drug name with prescribers if the prescription is not legible or the drug name is not clearly stated.
- Report adverse events or medication errors involving ropinirole or risperidone to the FDA MedWatch program, using the information in the "Contact Us" box at the bottom of the page.

**Data Summary**

FDA evaluated 226 wrong drug medication errors relating to confusion between risperidone and ropinirole obtained from FDA's Adverse Event Reporting System database and the Institute for Safe Medication Practices. Several cases resulted in adverse events (n=16), including 5 cases that resulted in hospitalization of the patients. The adverse events occurred due to the administration of incorrect medication and included confusion, lethargy, ataxia, hallucinations, tiredness, dizziness, tingling, numbness and altered mental status. In one of the cases reported from outside the United States, a patient was given Risperdal instead of Requip for one month before a care worker noticed the error. Requip was restarted without titration, and one month after Requip was restarted the patient died. It is unclear what role, if any, the error had in the death of this patient.

FDA determined the causes of confusion between risperidone and ropinirole are multi-factorial in nature. Contributing factors are orthographic similarity of the proprietary (brand) and established (generic) names, similar container labels and carton packaging, illegible handwriting, and overlapping strengths, dosage forms, and dosing intervals between the two products.

The incidence of confusion between the two products increased considerably after 2006 with the introduction of the generic products, which utilize the established (generic) names on the container labels. Generic risperidone was approved in 2006 and generic ropinirole was approved in 2008. However, FDA cannot rule out the possibility that the proprietary (brand) names also may have contributed to the confusion. All of the cases of confusion between risperidone and ropinirole involved tablet formulations.

In addition to the similarity in names, the products have overlapping characteristics, such as the same dosage form (tablet), frequency of dosing (daily or twice daily) and a numerical similarity in dosage strengths (0.25 mg, 0.5 mg, 1 mg, 2 mg, 3 mg, and 4 mg). It is also possible that the two products are stocked close to one another on pharmacy shelves, whether alphabetized by brand name or generic name. Moreover, some of the generic manufacturers make both products. The use of similar labels and carton packaging within the generic product lines by such manufacturers increases the likelihood of confusion between risperidone and ropinirole. Given similar labels and carton packaging designs used by many generic manufacturers, when this factor is combined with similarities in drug names, overlapping product characteristics, and proximity in stocking within pharmacies, there is considerable potential for product misidentification and medication errors.

Although for most of the cases the reporters did not state the source of the confusion, in two cases they attributed the cause of error to the similarity in the established (generic) names and overlapping strengths. In addition, proximity of the products on the pharmacy shelf and similar packaging were reported as contributing factors in two cases.

**Table 1. Ropinirole and Risperidone Product Similarities**

http://www.fda.gov/Drugs/DrugSafety/ucm258805.htm
Generic name

<table>
<thead>
<tr>
<th>Ropinirole</th>
<th>Risperidone</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brand name</td>
<td>Requip, Requip XL</td>
</tr>
<tr>
<td>Oral tablet:</td>
<td>0.25 mg, 0.5 mg, 1 mg, 2 mg, 3 mg, 4 mg, 5 mg</td>
</tr>
<tr>
<td>Extended-release tablet (XL):</td>
<td>2 mg, 4 mg, 6 mg, 8 mg, 12 mg</td>
</tr>
</tbody>
</table>

Strengths

Dosage form

<table>
<thead>
<tr>
<th>Ropinirole</th>
<th>Risperidone</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tablet</td>
<td>Tablet</td>
</tr>
</tbody>
</table>

Dosing intervals

<table>
<thead>
<tr>
<th>Ropinirole</th>
<th>Risperidone</th>
</tr>
</thead>
<tbody>
<tr>
<td>Once daily, Twice daily, or Three times daily</td>
<td>Once daily or Twice daily</td>
</tr>
</tbody>
</table>

Sample Container Labels

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Related Information

- [Atypical Antipsychotic Drugs Information](http://www.fda.gov/Drugs/DrugSafety/ucm258805.htm)
- [Ropinirole (marketed as Requip) Information](http://www.fda.gov/Drugs/DrugSafety/ucm258805.htm)
- [FDA Drug Safety Podcast for Healthcare Professionals: Medication errors resulting from confusion between risperidone (Risperdal) and ropinirole (Requip)](http://www.fda.gov/Drugs/DrugSafety/ucm258805.htm) [ARCHIVED]

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Regular Mail: Use postage-paid FDA Form 3500

Mail to: MedWatch 5600 Fishers Lane
Rockville, MD 20857
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