ASD Healthcare
AmerisourceBergen

3101 Gaylord Parkway
Frisco, TX 75034

800.746.6273
asdhealthcare.com

July 18, 2018

URGENT: Sandoz issues a voluntary recall for all lots of Ondansetron Orally Disintegrating Tablets (ODT) and Risperidone Orally Disintegrating Tablets (ODT)

Dear ASD Healthcare Customer:

Sanoz Inc. is voluntarily implementing a U.S. Consumer Product Safety Commission ("CPSC")-approved corrective action plan for blister packs of Sandoz Ondansetron Orally Disintegrating Tablets (ODT) in 4 mg and 8 mg dosage strengths and Risperidone Orally Disintegrating Tablets (ODT) in 0.5 mg, 1 mg, 2 mg, 3 mg and 4 mg dosage strengths. This action is not a result of any quality or safety concerns with the medications for their intended use and is in cooperation with the CPSC and Food and Drug Administration.

The blister cards in which Ondansetron ODT and Risperidone ODT are packaged are not child-resistant, posing a risk of harm if the tablets are swallowed by children. As a result, Sandoz is implementing a corrective action plan at the patient level in the United States. To avoid a potential drug shortage, Sandoz is providing child-resistant pouches to pharmacists in which to dispense the affected drugs. To avoid potential interruption of patients' current supply of medication and dosing regiment, Sandoz is offering patients child-resistant pouches in which to store the affected drugs already in patients' possession. This is an interim measure until the child-resistant packaging is available for household use

Sandoz provided the following affected information for all lots of the following NDC numbers

Product Description	Package Description	NDC Number on Carton	NDC Number on Blister Pack
Ondansetron ODT 4 mg	Blister packs of 30 tablets	00781-5238-64	00781-5238-06
Ondansetron ODT 8 mg	Blister packs of 10 tablets	00781-5239-80	00781-5239-06
Ondansetron ODT 8 mg	Blister packs of 30 tablets	00781-5239-64	00781-5239-06
Risperidone ODT 0.5 mg	Blister packs of 28 tablets	00781-5310-08	00781-5310-06
Risperidone ODT 1 mg	Blister packs of 28 tablets	00781-5311-08	00781-5311-06
Risperidone ODT 2 mg	Blister packs of 28 tablets	00781-5312-08	00781-5312-06
Risperidone ODT 3 mg	Blister packs of 28 tablets	00781-5313-08	00781-5313-06
Risperidone ODT 4 mg	Blister packs of 28 tablets	00781-5314-08	00781-5314-06

We ask for your cooperation in taking the following action:

Dispensing Sandoz Ondansetron ODT and Risperidone ODT
If you have not already received child-resistant pouches in which to dispense the affected Sandoz Ondansetron ODT and Risperidone ODT products to patients, stop dispensing until you have received such pouches. Please contact the Sandoz Fulfillment Center (Hibbert) toll-free at 800.897.0844 between 7:00 a.m. and 7:00 p.m. (CST) Monday-Friday or CPSCRecall@hibbertgroup.com and provide the following information to order the pouches:

- Pharmacy name and address where the drug product was dispensed
- Telephone number and average stock level of Sandoz Ondansetron ODT and Risperidone ODT blister cartons

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Hibbert will then ship to your location a quantity of child-resistant pouches via FedEx overnight. Future shipments of the Ondansetron ODT and Risperidone ODT products from ASD Healthcare will be accompanied with child-resistant pouches. However, please contact Hibbert toll-free at 800.897.0844 between 7:00 a.m. and 7:00 p.m. (CST) Monday-Friday or CPSCRecall@hibbertgroup.com for additional units of child-resistant pouches as needed to ensure you dispense the Sandoz Ondansetron ODT and Risperidone ODT products only in the child-resistant pouches.

Place the entire Sandoz Ondansetron ODT or Risperidone ODT prescription (including the carton if applicable) in the child-resistant pouches when dispensing to patients. Do not use the child-resistant pouches for any other drug products in your inventory. Sandoz will notify you when it is no longer necessary to dispense Sandoz Ondansetron ODT or Risperidone ODT products in the child-resistant pouches.

Additional information regarding this voluntary recall is available at www.us.sandoz.com/patients-customers/product-safety-notices. Instructions for using the child-resistant pouches themselves, and a video demonstrating their use is available at the recall website.

Retailer Posters

Please download and print copies of the retail posters available at www.us.sandoz.com/patients-customers/product-safety-notices to notify patients about the voluntary recall. **The CPSC requires retailers to display recall posters for at least 120 days from the date the recall is announced** in highly visible locations, such as the pharmacy counter, customer information bulletin boards, cash registers and entrances.

Patient Notification

To order a child-resistant pouch in which to place products that have already been dispensed, or to receive additional information about this voluntary recall, patients should call Sandoz at 888.NOW.NOVA (888.669.6682) between 7:00 a.m. and 7:00 p.m. (CST) Monday-Friday or visit www.us.sandoz.com/patients-customers/product-safety-notices.

Sandoz has asked for pharmacists to assist in notifying patients who may have received the Sandoz Ondansetron ODT and Risperidone ODT products. Please download and provide to patients the “Dear Patient” letter available at www.us.sandoz.com/patients-customers/product-safety-notices, which contains instructions to maintain Sandoz Ondansetron ODT and Risperidone ODT in the child-resistant pouch.

Other Information

Any medically related inquiries should be directed to Sandoz at 888.NOW.NOVA (888.669.6682) or visit www.us.sandoz.com/patients-customers/product-catalog. Please report any adverse events by calling Sandoz at 888.NOW.NOVA (888.669.6682) or by emailing Sandoz at ga.drugsafety@sandoz.com. Adverse events can also be reported to the FDA online at www.fda.gov/medwatch/report.htm.

Please contact ASD Healthcare Customer Service at 800.746.6273 with any questions.

For the full recall notice, please view the attached documents in the following pages.

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Sandoz Inc.
100 College Road West
Princeton, NJ 08540 USA
www.us.sandoz.com

DRUG PRODUCT RECALL

Sandoz Ondansetron Orally Disintegrating Tablets (ODT) and Risperidone Orally Disintegrating Tablets (ODT)

July 2018

Dear Pharmacist:

Sandoz Inc. ("Sandoz"), in cooperation with the U.S. Consumer Product Safety Commission ("CPSC") and Food and Drug Administration ("FDA"), is voluntarily implementing a CPSC-approved corrective action plan for blister packs of Sandoz Ondansetron Orally Disintegrating Tablets (ODT) in 4 mg and 8 mg dosage strengths and Risperidone Orally Disintegrating Tablets (ODT) in 0.5 mg, 1 mg, 2 mg, 3 mg and 4 mg dosage strengths distributed in the United States. **This action is not a result of any quality or safety concerns with the medications for their intended use.**

The blister cards in which Sandoz Ondansetron ODT and Risperidone ODT are packaged are not child-resistant, posing a risk of harm if the tablets are swallowed by children. As a result, Sandoz is implementing a corrective action plan to the patient level in the United States. To avoid a potential drug shortage, Sandoz is providing child-resistant pouches to pharmacists in which to dispense the affected drugs. To avoid potential interruption of patients' current supply of medication and dosing regimen, Sandoz is offering patients child-resistant pouches in which to store the affected drugs already in patients' possession. Patients may continue to use the products as directed. This is an interim measure until child resistant packaging is available for household use.

This notification applies to all lots of the following NDC numbers of Sandoz Risperidone ODT listed at www.us.sandoz.com/patients-customers/product-safety-notices:

Product	Tablet Strength	Package Description	NDC Number on Carton	NDC Number on Blister Pack
Ondansetron ODT	4 mg	Blister packs of 30 tablets	0781-5238-64	0781-5238-06
Ondansetron ODT	8 mg	Blister packs of 10 tablets	0781-5239-80	0781-5239-06
Ondansetron ODT	8 mg	Blister packs of 30 tablets	0781-5239-64	0781-5239-06
Risperidone ODT	0.5 mg	Blister packs of 28 tablets	0781-5310-08	0781-5310-06
Risperidone ODT	1 mg	Blister packs of 28 tablets	0781-5311-08	0781-5311-06
Risperidone ODT	2 mg	Blister packs of 28 tablets	0781-5312-08	0781-5312-06
Risperidone ODT	3 mg	Blister packs of 28 tablets	0781-5313-08	0781-5313-06
Risperidone ODT	4 mg	Blister packs of 28 tablets	0781-5314-08	0781-5314-06

PHARMACY ACTION:

Dispensing Sandoz Ondansetron ODT and Risperidone ODT

If you have not already received child-resistant pouches in which to dispense the affected Sandoz Ondansetron ODT and Risperidone ODT products patients, stop dispensing until you have received such pouches. Please contact the Sandoz Fulfillment Center (Hibbert) toll-free at (800) 897-0844 between 7:00 AM and 7:00 PM (CT) Monday-Friday or CPSCRecall@hibbertgroup.com and provide the following information to order the pouches:

- Pharmacy Name, Address where the drug product was dispensed
- Telephone Number, Average stock level of Sandoz Risperidone ODT blister cartons

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Sandoz Inc.
100 College Road West
Princeton, NJ 08540 USA
www.us.sandoz.com

Hibbert will then ship to your location a quantity of child-resistant pouches via FEDEX overnight. Future shipments of the Ondansetron ODT and Risperidone ODT products from your distributor may be accompanied by child-resistant pouches. However, please contact Hibbert toll-free at (800) 897-0844 between 7:00 AM and 7:00 PM (CT) Monday-Friday or CPSCRecall@hibbertgroup.com for additional units of child-resistant pouches as needed to ensure that you dispense the Sandoz Ondansetron ODT and Risperidone ODT products only in child-resistant pouches.

Place the entire Sandoz Ondansetron ODT or Risperidone ODT prescription (including the carton if applicable) in the child-resistant pouches when dispensing to patients. Do not use the child-resistant pouches for any other drug products in your inventory. Sandoz will notify you when it is no longer necessary to dispense Sandoz Ondansetron ODT or Risperidone ODT products in child-resistant pouches.

Additional information regarding this voluntary recall is available at **www.us.sandoz.com/patients-customers/product-safety-notices**. Instructions for using the child-resistant pouches are on the pouches themselves, and a video demonstrating their use is available at the recall website.

Retailer Posters

Please download and print copies of the retail posters available at www.us.sandoz.com/patients-customers/product-safety-notices to notify patients about the voluntary recall. **The CPSC requires retailers to display recall posters for at least 120 days from the date the recall is announced** in highly visible locations, such as at the pharmacy counter, customer information bulletin boards, cash registers, and entrances. The CPSC plans to announce the voluntary recall on July 5, 2018. **To help avoid confusion, it is important that announcement to the public be coordinated through the CPSC. Therefore, please begin to display these posters on the morning of July 5 and not before.**

Patient Notification

To order a child-resistant pouch in which to place products that already have been dispensed, or to receive additional information about this voluntary recall, patients should call Sandoz at 888-NOW-NOVA (888-669-6682) between 7:00 AM and 7:00 PM (CT) Monday-Friday or visit www.us.sandoz.com/patients-customers/product-safety-notices.

We also ask that you assist us in notifying patients who may have received the Sandoz Ondansetron ODT and Risperidone ODT products. Please download and provide to patients the "Dear Patient" Letter available at www.us.sandoz.com/patients-customers/product-safety-notices, which contains instructions to maintain Sandoz Ondansetron ODT and Risperidone ODT in the child-resistant pouch.

Other Information

Any medical related inquiries should be directed to Sandoz at 888-NOW-NOVA (888-669-6682) or visit www.us.sandoz.com/patients-customers/product-catalog. Please report any adverse events by calling Sandoz at the same phone number or by emailing Sandoz at qa.drugsafety@sandoz.com. Adverse events can also be reported to FDA online at www.fda.gov/medwatch/report.htm.

We appreciate your immediate attention and cooperation and apologize for this situation.

Sincerely,

Emma Harrington
Head, Novartis Country Quality US