Dr. Reddy’s Recalls Prescription Drug Blister Packages Due to Risk of Poisoning

Recall Summary

Name of Products: Imatinib Mesylate Tablets 100 mg, Imatinib Mesylate Tablets 400 mg, Pregabalin Capsules 50 mg, Pregabalin Capsules 75 mg, Pregabalin Capsules 100 mg, Pregabalin Capsules 150 mg, Sevelamer Carbonate Tablets 800 mg, Tadalafil Tablets 5 mg and Tadalafil Tablets 20 mg

Hazard: The products are prescription medications that were labeled and distributed by Dr. Reddy’s for institutional use only. The prescription medications were distributed by third party wholesalers to retail pharmacies and could have been dispensed to consumers. The packaging of the products is not child resistant and can pose a risk of poisoning if the contents are swallowed by young children.

Remedy: Refund

Consumers should immediately store the recalled medications in a safe location out of reach of children and contact Dr. Reddy’s for a full refund.

Consumer Contact:
Dr. Reddy’s toll-free at 888-375-3784 from 8 a.m. to 8 p.m. ET Monday through Friday, or online at www.drreddys.com and click on “Recall” for more information. Report incidents related to children accessing or ingesting these prescription medications to www.SaferProducts.gov. Report adverse events, medication errors, and quality problems related to the use of these products to FDA’s MedWatch Adverse Event Reporting Program either online at www.fda.gov/medwatch/report.htm, download the form at www.fda.gov/MedWatch/getforms.htm or call 800-332-1088 to request a reporting form, then complete and submit by regular mail, and return to the address on the pre-addressed form, or submit by fax to 800-FDA-0178.

Recall Details

Units: About 21,400

Description: This recall involves blister packages of prescription medications. The name and strength of the medication, “For Institutional Use only,” “Rx Only,” lot number and expiration date are printed on the outside of the package as well as on the individual blister units. The Dr. Reddy’s logo and
NDC number are printed on the outside of the package. The recalled medications include the following:

<table>
<thead>
<tr>
<th>Recalled Prescription Drugs</th>
<th>NDC Numbers</th>
<th>Carton Configurations</th>
<th>Lot Numbers</th>
<th>Expiration Dates</th>
</tr>
</thead>
<tbody>
<tr>
<td>Imatinib Mesylate Tablets 100 mg</td>
<td>43598-344-31</td>
<td>3 blister cards of 10 tablets</td>
<td>H2000138</td>
<td>2022-0630</td>
</tr>
<tr>
<td>Imatinib Mesylate Tablets 400 mg</td>
<td>43598-345-31</td>
<td>3 blister cards of 10 tablets</td>
<td>H2000127</td>
<td>2022-0630</td>
</tr>
<tr>
<td>Pregabalin Capsules 50 mg</td>
<td>43598-292-66</td>
<td>5 blister cards of 10 capsules</td>
<td>T900876</td>
<td>2021-0630</td>
</tr>
<tr>
<td>Pregabalin Capsules 75 mg</td>
<td>43598-293-66</td>
<td>5 blister cards of 10 capsules</td>
<td>T901021</td>
<td>2021-0731</td>
</tr>
<tr>
<td>Pregabalin Capsules 100 mg</td>
<td>43598-294-66</td>
<td>5 blister cards of 10 capsules</td>
<td>T901022</td>
<td>2021-0731</td>
</tr>
<tr>
<td>Pregabalin Capsules 150 mg</td>
<td>43598-295-66</td>
<td>5 blister cards of 10 capsules</td>
<td>T901023</td>
<td>2021-0731</td>
</tr>
<tr>
<td>Sevelamer Carbonate Tablets 800 mg</td>
<td>55111-789-11</td>
<td>4 blister cards of 25 tablets</td>
<td>T801003, T000009, T900221</td>
<td>2020-1031, 2021-1231, 2021-0228</td>
</tr>
<tr>
<td>Tadalafil Tablets 5 mg</td>
<td>43598-575-31</td>
<td>3 blister cards of 10 tablets</td>
<td>T000376</td>
<td>2022-0131</td>
</tr>
<tr>
<td>Tadalafil Tablets 20 mg</td>
<td>43598-573-31</td>
<td>3 blister cards of 10 tablets</td>
<td>T000425</td>
<td>2022-0228</td>
</tr>
</tbody>
</table>

**Incidents/Injuries:** No incidents or injuries have been reported.

**Sold At:** Beginning in 2018, Dr. Reddy’s sold the recalled medications to wholesalers. Ultimately, these medications could have been sold to consumers at retail pharmacies in the United States at prices varying based on quantities prescribed, health insurance terms, and other factors.

**Importer:** Dr. Reddy’s Laboratories, Inc., of Princeton, N.J.

**Manufacturer:** Dr. Reddy’s Laboratories, Ltd., of India

**Manufactured in:** India

**Photos**
Recalled Dr. Reddy’s Imatinib Mesylate Tablets 100 mg
Recalled Dr. Reddy’s Imatinib Mesylate Tablets 400 mg
Recalled Dr. Reddy’s Pregabalin Capsules 50 mg
Recalled Dr. Reddy’s Pregabalin Capsules 75 mg
Recalled Dr. Reddy's Pregabalin Capsules 100 mg

For Institutional Use only

Pregabalin Capsules, 100 mg

- This Unit Dose package is not child resistant.
- Keep this and all drugs out of the reach of children.

Rx only

50 Capsules (5 x 10 unit-dose)

Recalled Dr. Reddy's Pregabalin Capsules 150 mg

For Institutional Use only

Pregabalin Capsules, 150 mg

- This Unit Dose package is not child resistant.
- Keep this and all drugs out of the reach of children.

Rx only

50 Capsules (5 x 10 unit-dose)
Recalled Dr. Reddy’s Sevelamer Carbonate Tablets 800 mg
Recalled Dr. Reddy’s Tadalafil Tablets 5 mg
Recalled Dr. Reddy’s Tadalafil Tablets 20 mg

About the U.S. CPSC
The U.S. Consumer Product Safety Commission (CPSC) is charged with protecting the public from unreasonable risks of injury or death associated with the use of thousands of types of consumer products. Deaths, injuries, and property damage from consumer product incidents cost the nation more than $1 trillion annually. CPSC’s work to ensure the safety of consumer products has contributed to a decline in the rate of deaths and injuries associated with consumer products over the past 40 years.

Federal law bars any person from selling products subject to a publicly announced voluntary recall by a manufacturer or a mandatory recall ordered by the Commission.

For lifesaving information:
- Visit CPSC.gov.
- Sign up to receive our e-mail alerts.
- Follow us on Facebook, Instagram @USCPSC and Twitter @USCPSC.
- Call CPSC’s Hotline at 800-638-2772 (TTY 301-595-7054).
- Contact a media specialist.