U.S. Consumer Product Safety Commission – Recall

Release Date: February 25, 2021
Release Number: 21-089

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:

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

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

For Institutional Use only

NDC 43598-**344**-31

Imatinib Mesylate Tablets 100 mg*

Rx only

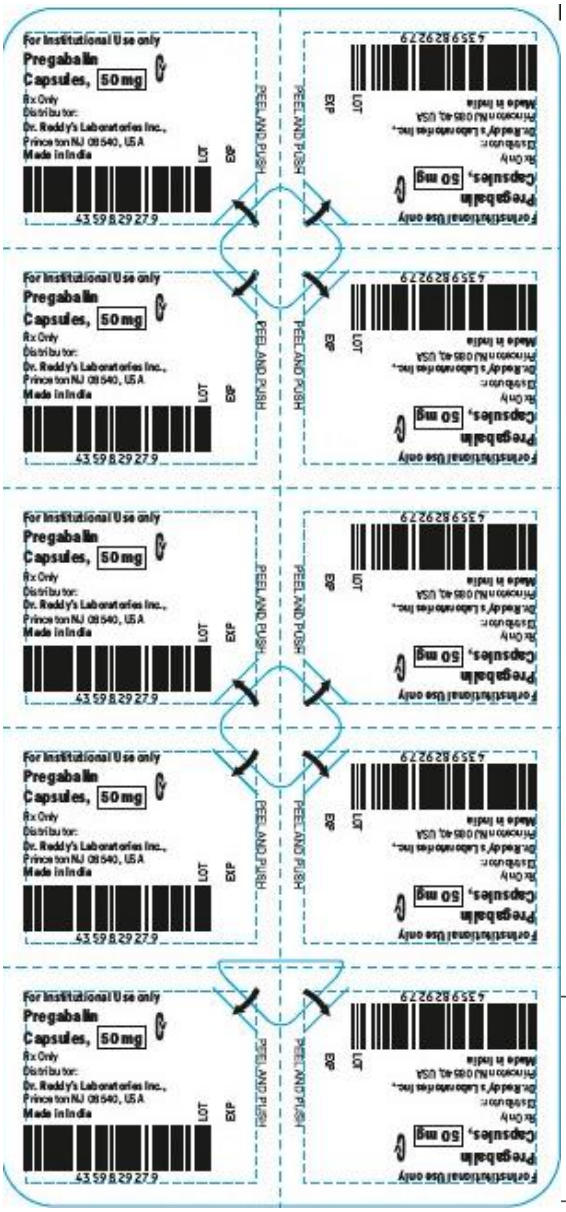
30 Tablets (3 x 10 unit-dose)

Dr.Reddy's

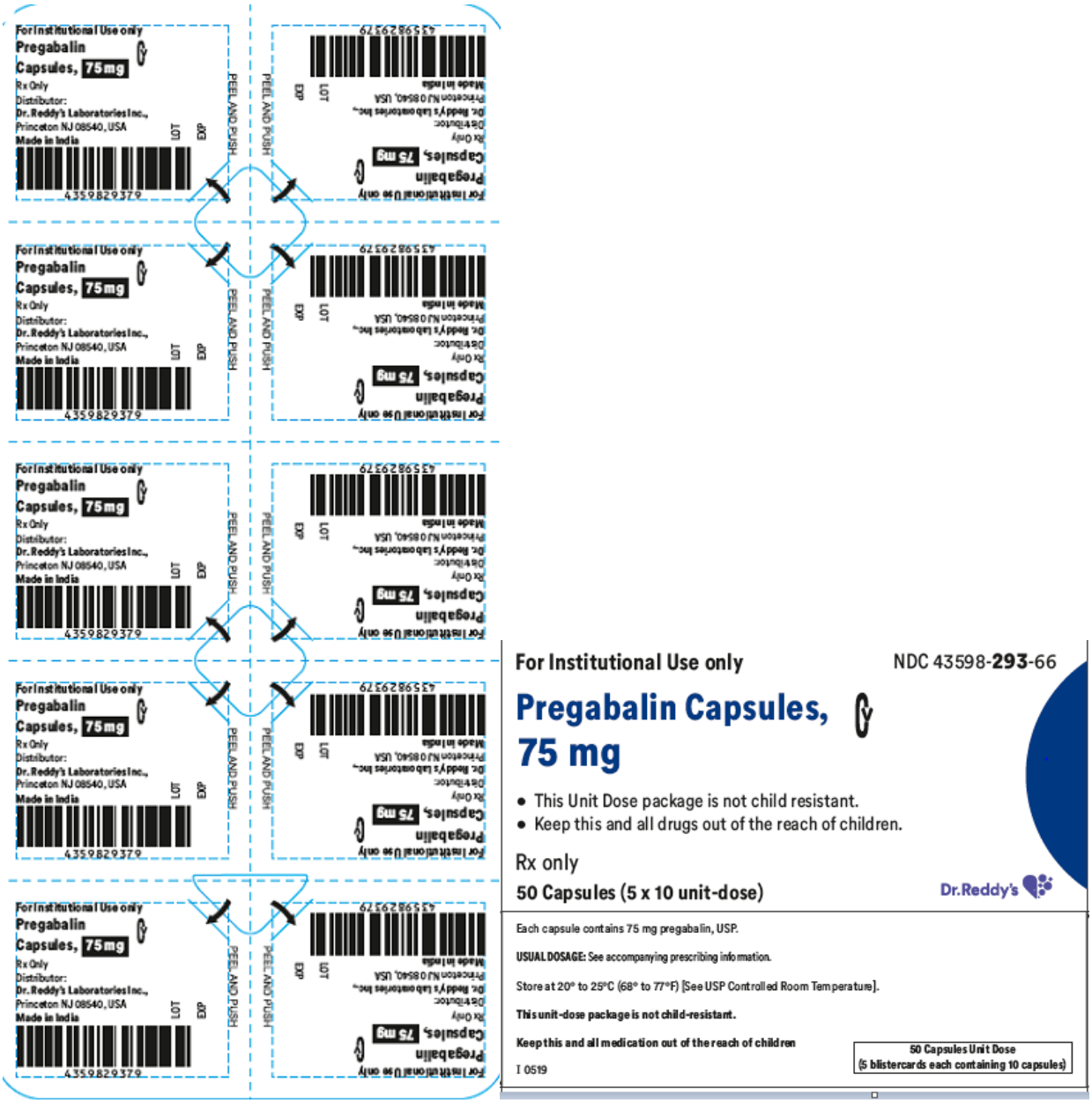
*Each film-coated tablet contains imatinib mesylate equivalent to imatinib 100 mg.
Usual Dosage: See package insert.
Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature]. Protect from moisture.
This unit-dose package is not child-resistant.
Keep this and all drugs out of the reach of children
I 1019

10 Tablets unit-dose
(3 blistercards each containing 10 tablets)

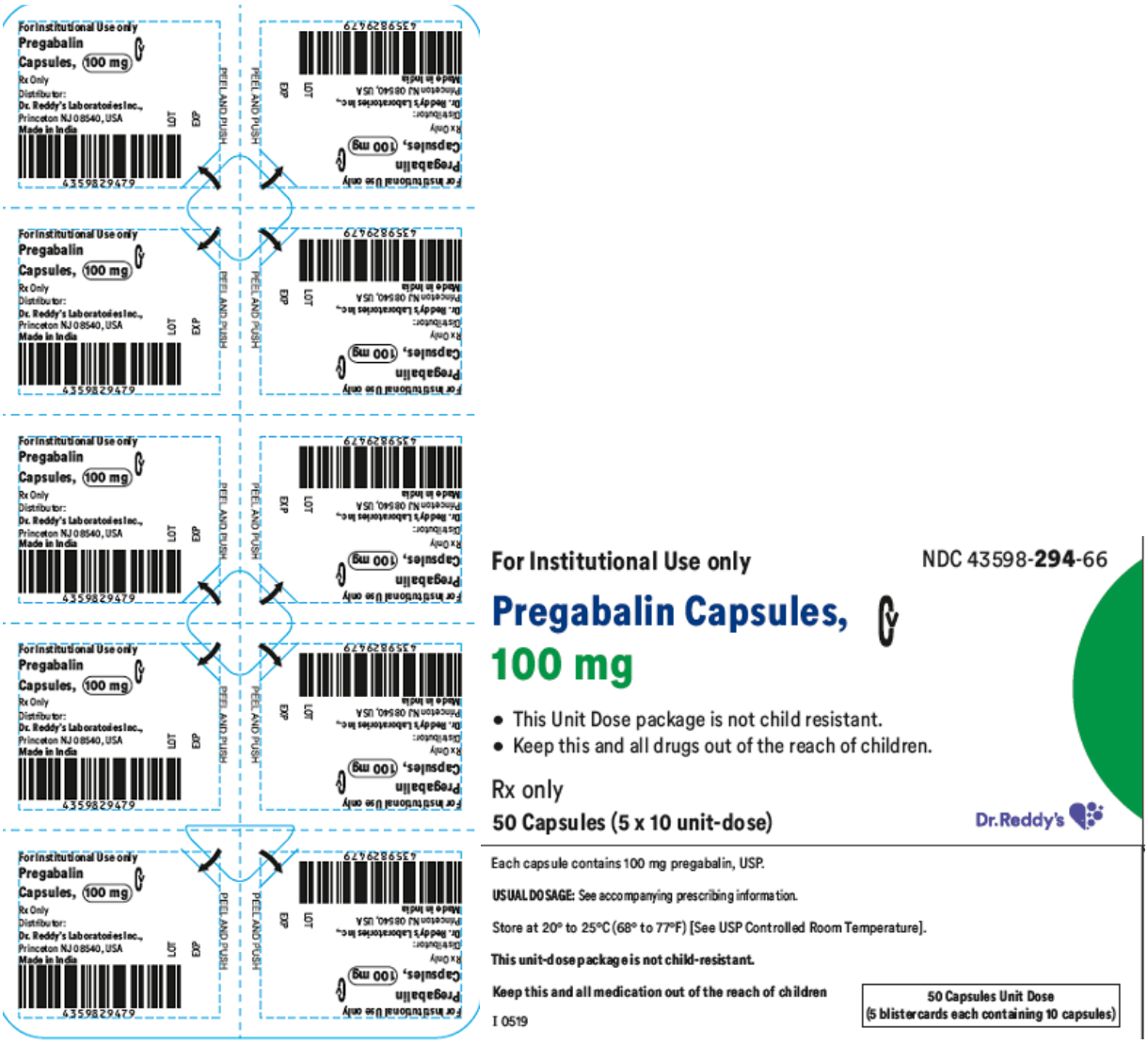
Recalled Dr. Reddy's Imatinib Mesylate Tablets 400 mg



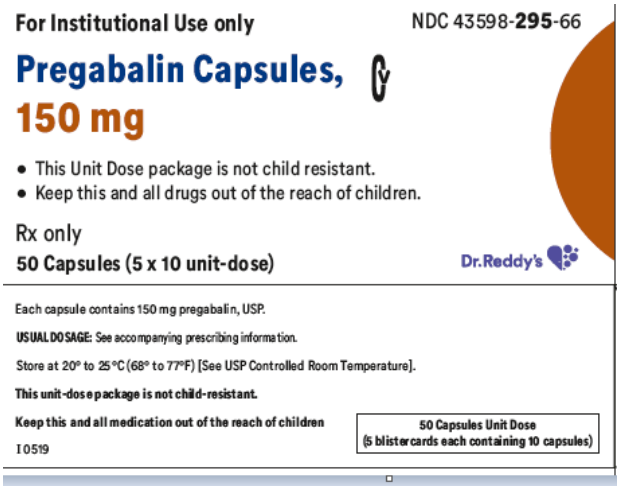
Recalled Dr. Reddy's Pregabalin Capsules 50 mg



Recalled Dr. Reddy's Pregabalin Capsules 75 mg

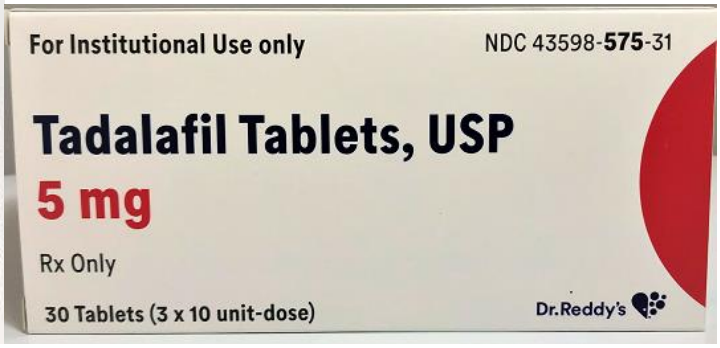


Recalled Dr. Reddy's Pregabalin Capsules 100 mg

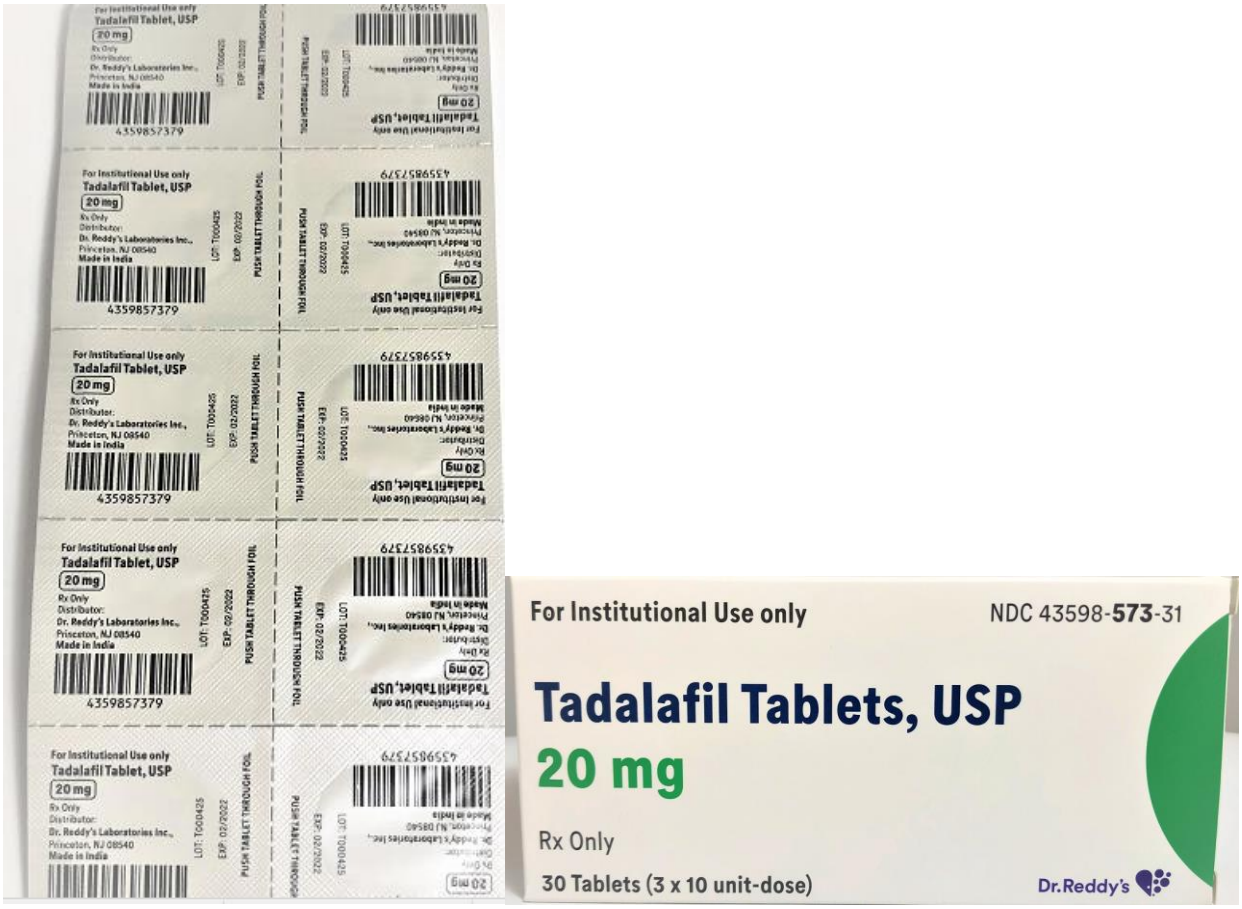


Recalled Dr. Reddy's Pregabalin Capsules 150 mg

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

Footer

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.

- Report a dangerous product or a product-related injury on www.SaferProducts.gov.
- Call CPSC's Hotline at 800-638-2772 (TTY 301-595-7054).
- Contact a media specialist.