Important Drug Recall Notice

TO ALL PARTICIPATING PHARMACIES

Circular Letter MC24-021-CG
April 25, 2024

FDA announced that Dr. Reddy's Laboratories Ltd. (BSE: 500124, NSE: DRREDDY, NYSE: RDY, NSEIFSC: DRREDDY, along with its subsidiaries together referred to as "Dr. Reddy's, is voluntarily **recalling six (6) lots of Sapropterin Dihydrochloride Powder for Oral Solution 100 mg** to the consumer level due to powder discoloration in some packets leading to decreased potency. The issue was discovered during an accelerated stability test in addition to customer complaints.

RECOMMENDATIONS

1. Dr. Reddy's Laboratories Inc. is notifying its distributors and customers by recall notification letters and is arranging for returns of all recalled products. Anyone with an existing inventory of the product being recalled should examine the product and quarantine any of the recalled lots immediately.
2. Consumers who have Sapropterin Dihydrochloride Powder for Oral Solution 100 mg which is being recalled should contact their physician before stopping use of the product.
3. Consumers who have Sapropterin Dihydrochloride Powder for Oral Solution 100 mg which is being recalled should return it to their place of purchase.
4. Consumers with questions regarding this recall can contact Dr. Reddy's Laboratories Inc. by calling **866-733-3952** during office hours from 9 a.m. to 5 p.m. (EST) Monday through Friday.
5. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product.
6. Please, review your inventory to identify existence of recalled products.
7. Expect patients to visit your pharmacy to deliver recalled products and prepare your pharmacy staff on how to handle the situation.

MC-Rx Pharmacy Services Department

T. (800) 377-1037
1267 Professional Pkwy, Gainesville, GA 30507
T. (787) 286-6032
Call Box 4908, Caguas, P.R. 00726
MC-Rx.com

FDA U.S. FOOD & DRUG ADMINISTRATION

Dr. Reddy's Issues Voluntary Nationwide Recall of Sapropterin Dihydrochloride Powder for Oral Solution 100 mg Due to Sub-Potency

SUMMARY:

Company Announcement Date:	April 23, 2024
FDA Publish Date:	April 23, 2024
Product Type:	Drugs
Reason for Announcement:	Decreased Potency
Company Name:	Dr. Reddy's Laboratories Inc
Brand Name:	Dr. Reddy's
Product Description:	Sapropterin Dihydrochloride Powder for Oral Solution 100 mg

COMPANY ANNOUNCEMENT

FOR IMMEDIATE RELEASE Hyderabad India and Princeton, NJ, US; April 23, 2024 – Dr. Reddy's Laboratories Ltd. (BSE: 500124, NSE: DRREDDY, NYSE: RDY, NSEIFSC: DRREDDY, along with its subsidiaries together referred to as "Dr. Reddy's"), today announced that it is voluntarily recalling six (6) lots of Sapropterin Dihydrochloride Powder for Oral Solution 100 mg to the consumer level due to powder discoloration in some packets leading to decreased potency. The issue was discovered during an accelerated stability test in addition to customer complaints.

Risk Statement: Reduced efficacy of the product would result in elevated Phenylalaninemia (Phe) levels in patients. Chronically elevated Phe levels in infants and children are likely to cause permanent neurocognitive deficits, including permanent and irreversible intellectual disability, developmental delay, and seizures. Furthermore, elevated Phe levels during pregnancy, especially in early gestation, are associated with microcephaly and congenital heart disease.

Dr. Reddy's Laboratories Inc. has not received any reports of adverse events related to this recall to date.

The product is indicated to reduce blood phenylalanine (Phe) levels in adult and pediatric patients one month of age and older with hyperphenylalaninemia (HPA) due to tetrahydrobiopterin-(BH4-) responsive Phenylketonuria (PKU) and is packaged in individual packets, 30 per carton. The affected Sapropterin Dihydrochloride Powder for Oral Solution 100mg lots include the following:

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Product Name	Lot Number	Expiration date	NDC Number
Javygtor™ (Sapropterin) Dihydrochloride) Powder for Oral Solution 100 mg	T2202812	07/2025	43598-097-30
	T2204053	10/2025	43598-097-30
	T2300975	02/2026	43598-097-30
	T2300976	02/2026	43598-097-30
	T2304356	08/2026	43598-097-30
Sapropterin Dihydrochloride Powder for Oral Solution 100 mg	T2200352	12/2024	43598-477-30

Sapropterin Dihydrochloride Powder for Oral Solution 100 mg was distributed nationwide to wholesalers/retailers.

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Consumers with questions regarding this recall can contact Dr. Reddy's Laboratories Inc. by calling 866-733-3952 during office hours from 9 a.m. to 5 p.m. (EST) Monday through Friday. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report Online
- Regular Mail or Fax: Download form or call 1- 800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

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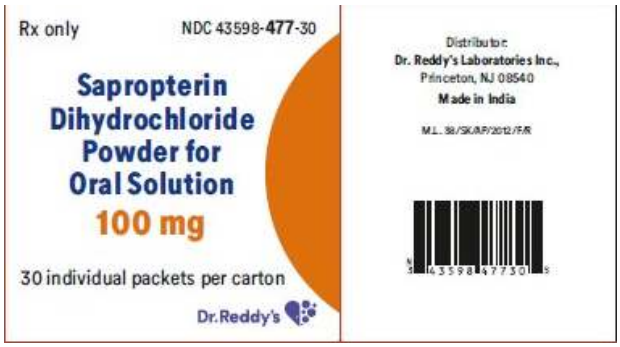

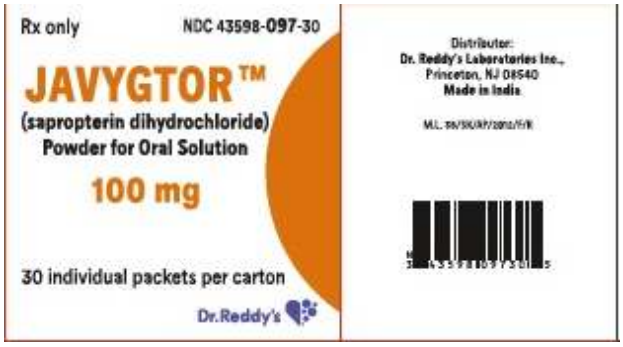

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