COMMUNICATION

COM-2024-031

24
April
2024

URGENT
PLEASE
REVIEW

Recall Notification

PharmPix Clinical Department

PharmPix is committed to the health and wellness of our members.

The clinical team wants to communicate the latest up-to-date drug recall information.

U.S. Food & Drug Administration Publication Date:

4/23/2024

Drug Information:

National Drug Code

43598-097-30

43598-477-30

Product Description:

SAPROPTERIN DIHYDROCHLORIDE POWDER FOR ORAL SOLUTION 100 MG

Lot Number

Refer to table included in the notification

Expiration Date

Refer to table included in the notification

Company:

DR. REDDY'S LABORATORIES INC.

QUESTIONS

Call DR. REDDY'S INC, at 866-733-3952 Monday – Friday, 9:00 am – 5:00 pm ET

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Sapropterin Dihydrochloride Powder

It is for this reason that we are notifying you that on 04.23.2024 the US Food and Drug Administration published a drug recall for the following product(s): Sapropterin Dihydrochloride Powder for Oral Solution 100 mg.

Pharmacy Required Action:

Identify if the product is in inventory and immediately stop using and dispensing it. The product should be returned to the place of purchase or as directed in the recall notification.

Advise patients that they should not discontinue using the medication without contacting their healthcare provider. Patients experiencing any problem while taking or using this product must contact their physician.

Reason for Recall:

Dr. Reddy's Laboratories Ltd. 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 affected Sapropterin Dihydrochloride Powder for Oral Solution 100mg lots include the following:

Product	Lot Number	Expiration Date	NDC (s)
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

Remember you can report adverse events related to this or any other drug product at MedWatch: The FDA Safety Information and Adverse Event Reporting Program by any of the following ways:

Complete and submit the MedWatch Online Voluntary Reporting Form online.

Download FDA Form 3500 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.

Additional information can be found at: MedWatch: The FDA Safety Information and Adverse Event Reporting Program.

If you have any questions or wish to have more information regarding this document, you can call us at 787-522-5252- Clinical Department. Our pharmacists will help you.

In addition, know that you can access our recent communications at our providers' portal: https://www.pharmpix.com/providers/.

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REFERENCES:

1. U.S. Food and Drug Administration. (2024). Dr. Reddy's Issues Voluntary Nationwide Recall of Sapropterin Dihydrochloride Powder for Oral Solution 100 mg Due to Sub-Potency from: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/dr-reddys-issues-voluntary-nationwide-recall-sapropterin-dihydrochloride-powder-oral-solution-100-mg
2. MedWatch: The FDA Safety Information and Adverse Event Reporting Program- Available at: https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/reporting-serious-problems-fda

urac ACCREDITED Pharmacy Benefit Management Expires 12/01/2025

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