Dr. Reddy’s Issues Voluntary Nationwide Recall of Sapropterin Dihydrochloride Powder for Oral Solution 100 mg

Date: 04/23/2024

About this recall:
Dr. Reddy's is voluntarily recalling 6 lots of Sapropterin Dihydrochloride Powder for Oral Solution 100 mg to the consumer level due to powder discoloration in some packets resulting in decreased drug potency. The problem was found during a stability test, in addition to customer complaints. Product lots being recalled carry the following NDC numbers: 43598-097-30 or 43598-477-30.

For lot recalls, the lot/batch information and expiration date for the recalled product can be viewed by clicking on the link to the FDA Recall Notification found on the following page.

This medication is FDA-approved to decrease blood phenylalanine (Phe) levels in certain adult and pediatric patients 1 month of age and older with elevated Phe levels. It is packaged in individual packets (30 per carton).

What this means to you:
Lower levels of sapropterin will lead to increased Phe levels. In infants and children if the Phe levels remain increased, permanent brain damage could occur, including irreversible intellectual disability, developmental delay, and seizures. Additionally, elevated levels during pregnancy, especially in early pregnancy, are associated with decreased head size and heart disease in the infant.

Consumers who have lots of sapropterin dihydrochloride powder for oral solution 100 mg which are being recalled should contact their healthcare professional before stopping use. Consumers who have a lot which is being recalled should return it to the place of purchase. Questions regarding this recall can be directed to Dr. Reddy’s by calling 866-733-3952 between 9 a.m. to 5 p.m. EST Monday through Friday. Patients should contact their healthcare professional 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.

This recall is being conducted with the knowledge of the United States (US) Food and Drug Administration.

For more information regarding this FDA Recall Notification, please refer to the FDA website: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/dr-reddys-issues-voluntary-nationwide-recall-sapropterin-dihydrochloride-powder-oral-solution-100-mg

FDA contact information for reporting adverse events/quality complaints can be reached online at https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home or by calling the FDA at 1-888-INFO-FDA (1-888-463-6332) and then selecting prompt #2.