

Dr. Reddy's – Recall of sapropterin powder for oral solution

- On April 23, 2024, [Dr. Reddy's announced](#) a consumer-level recall of six lots of [sapropterin powder for oral solution](#) because of powder discoloration in some packets leading to decreased potency. The issue was discovered during an accelerated stability test in addition to customer complaints.

Product Description	NDC number	Lot number (Exp Date)
Javygtor [™] (sapropterin) dihydrochloride) powder for oral solution 100 mg	43598-097-30	T2202812 (7/2025); T2204053 (10/2025); T2300975 (2/2026); T2300976 (2/2026); T2304356 (8/2026)
Sapropterin dihydrochloride powder for oral solution 100 mg	43598-477-30	T2200352 (12/2024)

- Sapropterin is indicated to reduce blood phenylalanine (Phe) levels in adult and pediatric patients one month of age and older with hyperphenylalaninemia due to tetrahydrobiopterin-(BH4-) responsive Phenylketonuria. Sapropterin dihydrochloride powder for oral solution is to be used in conjunction with a Phe-restricted diet.
- Reduced efficacy of the product would result in elevated 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.
- To date, Dr. Reddy's has not received any reports of adverse events related to this recall.
- Patients with affected product on hand should contact their provider before stopping use and return recalled product to their pharmacy. Patients should contact their healthcare provider if they have experienced any problems that may be related to using the recalled product.
- Anyone with an existing inventory of the product being recalled should examine the product and quarantine any of the recalled lots immediately.
- Consumers may contact Dr. Reddy's at **1-866-733-3952** for more information.