

Drug Recall

DATE OF RECALL: April 23, 2024

DRUG NAME: Sapropterin Powder for Oral Solution

RECALLING FIRM: Dr Reddy's.

REASON FOR RECALL: 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.

FDA LINK: <https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/dr-reddys-issues-voluntary-nationwide-recall-sapropterin-dihydrochloride-powder-oral-solution-100-mg>

OTHER DETAILS: N/A

RECALLED PRODUCT:

Product Description	NDC Number	Lot Number	Expiration Date
Javygtor™ (sapropterin) 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 powder for oral solution 100 mg	43598-477-30	T2200352	(12/2024)