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Voluntary Recall of JAVYGTOR™ (sapropterin dihydrochloride) Powder for Oral Solution 100 mg

Dr Reddy's Laboratories Ltd (Dr Reddy's) today announced that it is voluntarily recalling all lots of Sapropterin Dihydrochloride Powder for Oral Solution 100 mg to the consumer level due to the potential of powder discoloration in some packets associated with decreased potency.

This includes lots branded as JAVYGTOR™, marketed by Cycle Pharmaceuticals Limited (Cycle) with patient services provided by Cycle VITA™.

Discoloration

- The discoloration of some sachets was discovered following four complaints received from two customers in the United States, in addition to observations during stability testing of the product.
- Dr Reddy's and Cycle have not received any reports of adverse events related to this recall to date.
- The discoloration is known to be isolated to a very small number of individual sachets and the majority of sachets are unaffected. The effected sachets are reported to be dark yellow to brown, in contrast to unaffected powder which is off white to pale yellow. The discoloration is clearly visible to the naked eye.
- An investigation performed by Dr. Reddy's found that discoloration was caused during the manufacturing process, specifically duration of heat exposure when sealing sachets.
- The discoloration issue and associated recall is isolated to the 100 mg strength of Powder for Oral Solution. The other JAVYGTOR products, Powder for Oral Solution 500 mg and Tablet 100 mg, are unaffected.

Affected Consumers

- Dr Reddy's, working with the FDA, has advised consumers who have Sapropterin Dihydrochloride Powder for Oral Solution 100 mg which is being recalled to contact their physician before stopping use of the product. As such, patients should reach out to their providers and providers may be contacted by your patients regarding this recall to discuss therapy plan.
- Cycle is currently working with Dr Reddy's to address the discoloration to restock Sapropterin Dihydrochloride Powder for Oral Solution 100 mg. Until it becomes available again, Cycle offers Tablet 100 mg and Powder for Oral Solution 500 mg as alternative and replacement.

The full press release from Dr Reddy's is available here:

<https://www.drreddys.com/cms/cms/sites/default/files/2024-04/Press%20Release%20-%20Sapropterin%20Powder.pdf>

Full prescribing information for JAVYGTOR (sapropterin dihydrochloride) Product is available here:

https://javygtor.com/JAVYGTOR_DIGITAL_PI.pdf



Sincerely,

A handwritten signature in black ink, appearing to read "Chikai Lai", with a long horizontal flourish extending to the right.

Chikai Lai

Chief Commercial Officer

Cycle Pharmaceuticals, Inc.