KVK Tech Issues Voluntary Nationwide Recall of Atovaquone Oral Suspension, USP 750 mg/5 mL Due to Temperature Abuse

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At Magellan Rx Management, we want to help you get the best possible care. We have created a site to share drug recall information.

KVK Tech has posted a lot recall of Atovaquone Oral Suspension 750 mg/5 mL.

About this recall:
KVK Tech is voluntarily recalling 2 lots of Atovaquone Oral Suspension, USP 750 mg/5 mL to the consumer level. The recall is based on customer complaints of unusual grittiness in the product, which KVK has determined was most probably caused by prolonged exposure of these product lots to extremely cold weather during shipment.

What this means to you:
Atovaquone is a prescription drug used to treat *Pneumocystis jiroveci* [*Pneumocystis carinii*] pneumonia, a type of pneumonia most likely to affect people with human immunodeficiency virus (HIV) in teenagers and adults, and is also used to prevent patients with weakened immune systems from contracting this type of pneumonia.

Exposure of atovaquone oral suspension to extremely low temperatures may result in changes to the effectiveness, appearance, taste, and thickness of the liquid. As the product is required to be protected from freezing temperatures, severely immunocompromised patients who receive less effective drug may not have their serious or life-threatening infection treated adequately. To date, KVK Tech is not aware of any adverse events associated with this problem.

The product is packaged in 8 oz. bottles (210 mL bottle with child-resistant cap) packaged in a carton with NDC # 10702-223-21; the affected lots are labeled 16653A and 16654A with both lots having expiration dates of December 2022. The lot numbers and expiration dates can be found on the right bottom side of the labels on the bottles.

Patients or caregivers who have bottles of recalled atovaquone should stop using and should return the product to KVK Tech at 110 Terry Drive, Newtown, PA 18940. KVK Tech will arrange to reimburse customers for their costs in purchasing the product.

Consumers with questions regarding this recall can contact KVK Tech at 215-579-1842 Ext: 6002, Monday through Friday, 8 am to 4:30 pm EST or via email at recall@kvktech.com. Consumers should contact their physician or 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/kvk-tech-inc-issues-voluntary-nationwide-recall-atovaquone-oral-suspension-usp-750-mg5ml-due

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.