



<<Date>>

<<First Name>> <<Last Name>>

<< Address line 1>>

<< Address line 2>>

<<City>> <<ST>> << Zip Code>>

IMPORTANT RECALL INFORMATION

Dear <<First Name>> <<Last Name>>,

On August 6, 2021, the United States Food and Drug Administration (FDA) published a notice regarding a recall of Atovaquone Oral Suspension, 750 mg/5 mL, NDC #10702-0223-21. **This recall was issued because of complaints of unusual grittiness in the product, which KVK Tech, Inc. (the manufacturer) has determined was most probably caused by prolonged exposure of these product lots to extremely cold weather during shipment.**

This recall affects lot numbers 16653A exp. 12/2022 and 16654A exp. 12/2022. No other lots are affected by this recall.

These products may represent a potential health hazard or safety risk to patients administered product affected by this recall.

Exposure of Atovaquone Oral Suspension to extremely low temperatures, during shipment may result in changes to the effectiveness, appearance, taste and thickness of the liquid. Severely immunocompromised patients who receive less effective Atovaquone Oral Suspension may experience inadequate treatment of serious and life-threatening infections.

If the product you have is not from one of these affected lot numbers, it is not affected by this recall. If your product is from one of these affected lot numbers, please contact the pharmacy that filled your prescription for further instructions.

You should check with your doctor immediately for advice on when to safely discontinue affected product. Your doctor knows your medical history and can tell you what to do next. If you need a prescription for a different product, please contact your doctor.

For more information, please call KVK Tech at 215-579-1842, ext. 6002, Monday – Friday, 8:00 AM – 4:30 PM (EST) or email them at recall@kvktech.com. You may also call the U.S. Food and Drug Administration toll-free at 1-888-INFO-FDA (1-888-463-6332) or visit www.fda.gov.

- This material is available in other languages. Please call our member services department at the toll-free number listed on your benefit ID card. TTY users should call 1-800-863-5488.

This document contains references to brand-name prescription drugs that are trademarks or registered trademarks of pharmaceutical manufacturers not affiliated with CVS Caremark. Your privacy is important to us. Our employees are trained regarding the appropriate way to handle your private health information. This information is not a substitute for medical advice or treatment. Talk to your doctor or health care provider about this information and any health-related questions you have. CVS Caremark assumes no liability whatsoever for the information provided or for any diagnosis or treatment made as a result of this information.

- Esta información está disponible en otros idiomas. Por favor llame a nuestro departamento de servicios al cliente al número gratuito que aparece en su tarjeta de identificación. Los usuarios de equipo teleescritor (TTY) deben llamar al 1-800-863-5488.

Sincerely,

CVS Caremark® Medical Affairs