

Tetracycline capsules Recall Alert

Date of Notice: 04/15/2020

Brief Description of Recall

On April 15, 2020, Avet Pharmaceuticals, Inc. issued a voluntary recall of tetracycline capsules due to low dissolution results. These products are manufactured by Avet Pharmaceuticals, Inc. and distributed under Heritage Pharmaceuticals, Inc. labeling.

Low dissolution results in less tetracycline available in the body to fight infection. This can lead to treatment failures. For patients with compromised immune systems and the elderly, who may be taking tetracycline to treat a serious infection such as pneumonia, there is a reasonable probability that if there is not enough tetracycline in the body to fight the infection, this could result in rapid progression of the infection and death.

Affected Products

Drug Name & Strength	NDC	Lot	Expiration Date
tetracycline 250mg capsules	23155-017-01	H190555	07/2022
tetracycline 500mg capsules	23155-018-01	G190609 G190610 G190611	06/2022
		K190952 K190953	10/2022
		L191027 L191028	11/2022

Prescriber Information

Pharmacies and healthcare facilities that have the drug subject to this recall should immediately stop dispensing this drug. To date, Avet has not received adverse event reports or complaints related to this event.

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: <u>Download form</u> 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 1-800FDA-0178

This document is designed to be an informational resource to facilitate discussion and should be used neither as a basis for clinical decision-making or treatment nor as a substitute for reading original literature. RxAdvance makes every effort to ensure that the information provided is up-to-date, accurate, and complete, but no guarantee is made to that effect. If this information is provided to clients or vendors, it is subject to any contractual confidentiality provisions. Third-party disclosures are in violation of confidentiality provisions.

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Member Information

Members should contact their prescriber for further guidance and potential change of treatment before they stop taking this drug.

Members with questions regarding this recall should contact Qualanex at 1-888-424-4341 Monday – Friday, 8:00 am – 5:00 pm, EST and/or recall@qualanex.com.

Members should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product.

RxAdvance Response

RxAdvance is in the process of contacting members and prescribers to advise them of this recall.

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