COMPANY ANNOUNCEMENT

Avet Pharmaceuticals Inc. Issues Voluntary Nationwide Recall of Tetracycline HCl Capsules USP, 250 mg and 500 mg Due to Failed Dissolution Specifications

Summary

Company Announcement Date:

April 15, 2020

FDA Publish Date:

April 16, 2020

Product Type:

Drugs

Reason for Announcement:

Due to low out of specification dissolution results

Company Name:

Avet Pharmaceuticals Labs Inc.

Brand Name:

Heritage

Product Description:

Tetracycline HCl Capsules, 250mg and 500mg

Company Announcement

Avet Pharmaceuticals Inc. (“Avet”), based in East Brunswick, New Jersey, is initiating a voluntary recall of the following lots of Tetracycline HCl Capsules USP, 250 mg and 500 mg, 100-count bottles listed in the table below to the consumer/user level.

Product	NDC Number	Lot No	Expiry Date

Tetracycline HCl Capsules 250 mg 100 count	23155-017-01	H190666	JUL 2022
Tetracycline HCl Capsules 500 mg 100 count	23155-018-01	G190609	JUN 2022
Tetracycline HCl Capsules 500 mg 100 count	23155-018-01	G190610	JUN 2022
Tetracycline HCl Capsules 500 mg 100 count	23155-018-01	G190611	JUN 2022
Tetracycline HCl Capsules 500 mg 100 count	23155-018-01	L191027	NOV 2022
Tetracycline HCl Capsules 500 mg 100 count	23155-018-01	L191028	NOV 2022
Tetracycline HCl Capsules 500 mg 100 count	23155-018-01	K190953	OCT 2022
Tetracycline HCl Capsules 500 mg 100 count	23155-018-01	K190952	OCT 2022

These drug products are manufactured by Avet Pharmaceuticals Labs Inc. and distributed under the Heritage Pharmaceuticals Inc. label. The voluntary recall is being initiated due to low out of specification dissolution test results.

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. To date, Avet has not received adverse event reports or complaints related to this event.

Tetracycline HCl Capsules USP, 250 mg and 500 mg are indicated in the treatment of infections caused by susceptible strains of the designated organisms, including upper and lower respiratory infections, skin and soft tissues infections, infections caused by Rickettsiae, as adjunctive therapy in severe acne. The recalled Tetracycline HCl Capsules 250 mg and 500 mg lots were distributed to wholesalers and distributors Nationwide in United States between August 2019 and March 2020.

Avet is notifying its distributors and customers by a separate notification to distributors and through Qualanex and is arranging for the return of all recalled products. Consumers should contact their doctor for further guidance and potential change of treatment before they stop taking this drug product. Pharmacies and healthcare facilities that have the drug product subject to this recall should immediately stop dispensing this drug product.

Consumers 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 (mailto:recall@qualanex.com). Consumers should contact their physician or healthcare provider 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 (/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/reporting-serious-problems-fda)
- Regular Mail or Fax: Download form (/safety/medical-product-safety-information/medwatch-forms-fda-safety-reporting) 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 U.S. Food and Drug Administration.

Company Contact Information

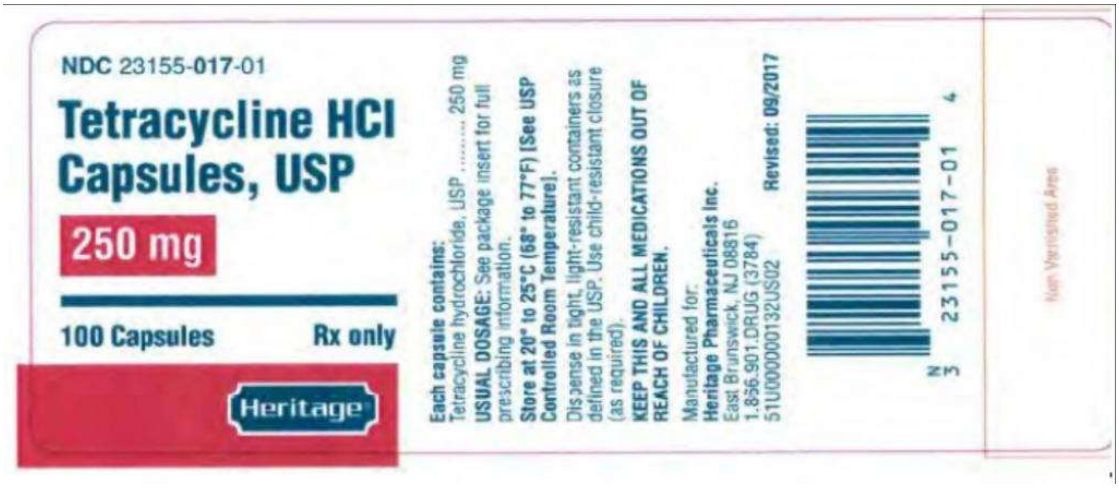
Consumers:

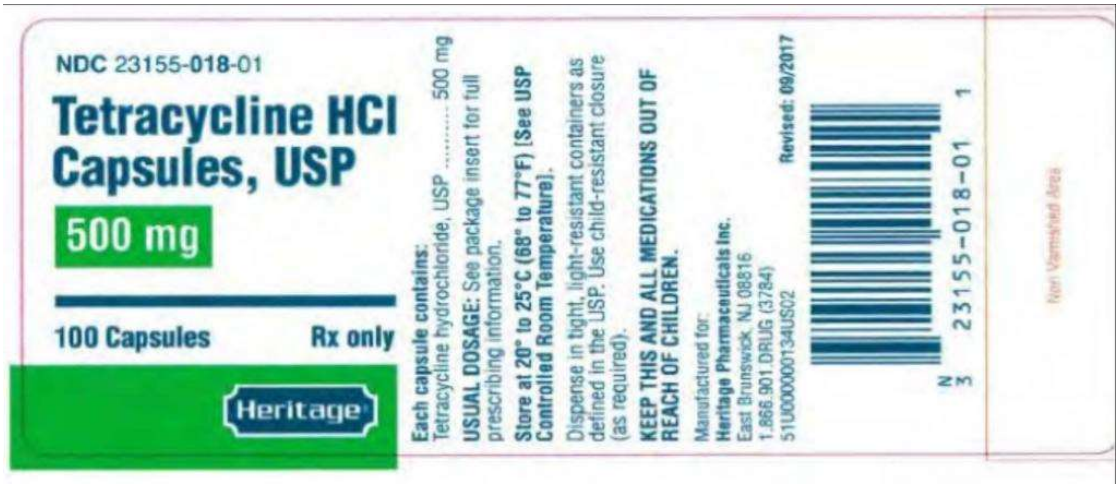
Avet Pharmaceuticals Inc.

1-888-424-4341

recall@qualanex.com (mailto:recall@qualanex.com)

Product Photos





More Recalls, Market Withdrawals, & Safety Alerts (/safety/recalls-market-withdrawals-safety-alerts)