

April 17, 2020

COM-2020-030

RECALL NOTIFICATION



DATE:
April 16, 2020

DRUG NAME:
Tetracycline HCl
Capsules, 250mg and
500mg

COMPANY:
Avet Pharmaceuticals
Labs Inc.

REASON:
Low out of specification
dissolution results

Dear provider of pharmaceutical services,

At PharmPix we are committed to the health and well-being of patients. The clinical team wants to communicate you with the latest up-to-date information on the Food and Drug Administration (FDA) drug recalls.

Affected product:

NDC	Product description	Lot #	Expiration date
23155-017-01	Tetracycline HCl Capsules 500 mg 100 count	G190609	JUN 2022
		G190610	JUN 2022
		G190611	JUN 2022
		L191027	NOV 2022
		L191028	NOV 2022
		K190953	OCT 2022
23155-018-01	Tetracycline HCl Capsules 250 mg 100 count	K190952	OCT 2022
		H190666	JUL 2022

Pharmacy required action:

- Identify if they have the product in inventory and immediately stop using and dispensing it.
- Contact all members that in the previous 90 days received the recalled medication and advise them to return the drug and contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using the recalled drug product.



Contact information:

- Consumers: Contact Qualanex at 1-888-424-4341. Monday – Friday, 8:00 am – 5:00 pm, EST and or recall@qualanex.com.

Note:

Remember that any adverse event related to this or any other pharmaceutical product can be reported to the FDA's MedWatch

Adverse Event Reporting program:

- Online: www.fda.gov/medwatch/report.htm
- Regular Mail or Fax: Download form www.fda.gov/MedWatch/getforms.htm 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

Additional information:

<https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/avet-pharmaceuticals-inc-issues-voluntary-nationwide-recall-tetracycline-hcl-capsules-usp-250-mg-and>

Best regards,

PharmPix Clinical Department

Reference:

- Center for Drug Evaluation and Research. (2020, April 16). Avet Pharmaceuticals Inc. Issues Voluntary Nationwide Recall of Tetracycline HCl Capsules USP, 250 mg and 500 mg Due to Failed Dissolution Specifications. Available at: <https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/avet-pharmaceuticals-inc-issues-voluntary-nationwide-recall-tetracycline-hcl-capsules-usp-250-mg-and>

