Teva Issues Voluntary Nationwide Recall of One Lot of Anagrelide Capsules, USP 0.5 mg Due to Dissolution Test Failure

FDA Publish Date: 05/23/2022

Teva Pharmaceuticals USA has initiated a voluntary nationwide recall of a single lot of Anagrelide Capsules, USP 0.5 mg (Lot number GD01090), to the consumer level in the United States. This voluntary recall was initiated due to dissolution test failure detected during routine stability testing. No other lots are impacted.

Administration of this product with lower dissolution – taking longer to dissolve once ingested -- may result in decreased effectiveness or ineffectiveness of the drug to exert its platelet-reducing effect. Failed dissolution can result in a slower rate and extent of drug release leading to less anagrelide available in the body. For seriously ill patients with elevated platelet counts, less available anagrelide in the body could increase the risk of clotting (blood coagulation), and clotting or bleeding events such as a heart attack or stroke, which could be life threatening. To date, Teva has not received any product quality complaints or adverse event reports, of this nature, for the recalled lot.

Anagrelide capsules are indicated for the treatment of patients with thrombocythemia, secondary to myeloproliferative neoplasms, to reduce the elevated platelet count and the risk of thrombosis and to ameliorate associated symptoms including thrombo-hemorrhagic events. Information about the affected lot is listed in the table below. It is packed in bottles with 100 capsules. Teva distributed 4,224 bottles nationwide from 07-30-2020 through 09-02-2020 to its wholesale, distributor, and retail customers under the label for Teva Pharmaceuticals USA, Inc.

NDC	Lot #	Exp. Date
0172-5241-60	GD01090	05/2022

Teva notified its customers on May 11, 2022, alerting them that the lot was recalled and requesting that they return impacted product. Instructions for returning recalled product and receiving a credit are given in the **customer recall letter (Anagrelide Recall 05 2022 Direct Accounts Letter Consumer Level 20 MAY 2022.pdf) and consumer recall letter (Anagrelide Recall 05 2022 _Patient Letter 20 MAY 2022.pdf)** released by Teva.

Consumers with questions or concerns should first consult with their health care provider(s). To report an Adverse Event or Quality Complaint, or if you have Medical Related Questions, please use the following contact information:

Medical-related Questions or to report an Adverse Event: Contact Medical Information at: 888-838-2872, option 3, then, option 4 Live calls received: M - F, 9:00 AM - 5:00 PM Eastern Time; Voicemail: 24 hrs./day, 7 days/week 24 hrs. /day, 7 days/week or by email at druginfo@tevapharm.com.
Product Quality Complaint-related Questions: Contact Quality Assurance Services: 888-838-2872, option 4 Live calls received: M - F, 9:00 AM - 5:00 PM Eastern Time; Voicemail: 24 hrs./day, 7 days/week

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 U.S. Food and Drug Administration.

This recall communication is from the FDA: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/teva-issues-voluntary-nationwide-recall-one-lot-anagrelide-capsules-usp-05-mg-due-dissolution-test

---

Company Contact Information

Consumers:

888-838-2872, option 4

druginfo@tevapharm.com

Media:

Kelley Dougherty

973-658-0237

Product Photos

Click here for product photos.