Important Drug Recall Notice

TO ALL PARTICIPATING PHARMACIES

Circular Letter MC22-055-CG
May 25, 2022

FDA announced that, Parsippany, NJ. 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.

RECOMMENDATIONS

1. 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 released by Teva.

2. 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.

    a. 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 hours/day, 7 days/week 24 hrs. /day, 7 days/week or by email at druginfo@tevapharm.com

3. Review your inventory to identify existence of recalled products.

4. Expect patients to visit your pharmacy to deliver recalled products and prepare your pharmacy staff on how to handle the situation.

5.

MC-Rx Pharmacy Services Department

T. (800) 377-1037
1267 Professional Pkwy, Gainesville, GA 30507
T. (787) 286-6032
Call Box 4908, Caguas, P.R. 00726
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FDA U.S. FOOD & DRUG ADMINISTRATION

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

Summary:

Company Announcement Date:	May 20, 2022
FDA Publish Date:	May 23, 2022
Product Type:	Drugs
Reason for Announcement:	Dissolution Test Failure
Company Name:	Teva Pharmaceuticals USA
Brand Name:	Teva
Product Description:	Anagrelide Capsules

Company Announcement

Parsippany, NJ. 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 4224 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.

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

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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

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