URGENT DRUG RECALL - Updated
Anagrelide Capsules, USP 0.5 mg, 100 Capsules
Initiated 05/11/2022; Updated 05/20/2022

Teva Pharmaceuticals USA, Inc.

Dear Valued Customer:

On 05/11/2022, Teva Pharmaceuticals USA, Inc. (Teva USA) has initiated a voluntarily nationwide recall of a single lot of **Anagrelide Capsules, USP 0.5 mg** to the retail level in the United States. This voluntary recall has now been extended to the Consumer/User Level. As previously communicated, the affected product lot number GD01090 was distributed under the label of Teva Pharmaceuticals USA, Inc. No other lots are impacted.

NDC	Lot	Exp. Date	Size	Teva USA Distribution
0172-5241-60	GD01090	05/2022	100 Capsules/Bottle	07/30/2020 - 09/02/2020

As stated in our 05/11/2022 recall communication, this recall has been initiated because dissolution results for routine stability testing of lot number GD01090 are below approved specification limits. 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.

Please take the following necessary **ACTIONS** stated below.

ACTIONS: Please *promptly* perform the following actions that are necessary for this recall:

- Examine your inventory for the recalled product lot GD01090.
- Quarantine and cease distribution of the recalled product lot GD01090.
- *Even if you have **no** product to return*, it is necessary that you ***promptly complete*** the attached recall stock response form (SRF) and ***promptly return*** the SRF by mail, email, or FAX to Inmar, Attn: Recall Coordinator,

  Inmar, 635 Vine Street, Winston Salem, NC 27101.

  Email address: **rxrecalls@inmar.com** FAX: 817-868-5362.
- **If you have further distributed product lots affected by this recall please, perform a SUB-RECALL to your accounts using this Recall Notification and Stock Response Form as a basis of your recall notification.**
- A letter of Recall Information for Consumers/Patients/Caregivers accompanies this recall communication. Teva requests that you provide a copy of this Information letter to Consumers/Patients/Caregivers that may contact you regarding this recall.

After receipt of your completed SRF, Inmar will send labels for Return Goods Authorization (RGA) and for return shipping of the recalled merchandise. Appropriate credit for your product returns, plus handling and shipping expenses, will be issued after receipt of said product and your RGA. All recalled product returned without a RGA may delay the issuance of a credit. Products returned that are not the subject of the recall will not be credited and will be destroyed.

CONTACT INFORMATION AND CREDIT
Product Returns: Contact Inmar at: 866-431-5972 (Dedicated Phone Line) for Recall Stock Response Forms (Hours of Operation: 9 am to 5 pm Eastern Time) or acquire forms from clsnetlink.com.
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 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
Customer Service-related Questions: Contact Teva Customer Service: 888-838-2872, option 3 then, option 2 Live calls received: M - F, 8:30 AM - 5:00 PM Eastern Time; Voicemail: 24 hrs./day, 7 days/week
FDA contact information for reporting adverse events/quality complaints: Online at www.fda.gov/medwatch/report.htm or call FDA at 1-800-FDA-1088

This recall is being made with the knowledge of the Food and Drug Administration.

Sincerely,

Regulatory Compliance, Teva Pharmaceuticals USA, Inc.
/enclosures: Stock Response Form

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STOCK RESPONSE FORM

Enter the information of the recalled product to be returned in the table below. If additional space is needed, please make copies of this form.

Please fill out completely **Date:** _____

DIRECT CUSTOMERS ONLY: Does this response include **all** your DC locations? ☐ YES ☐ NO

Customer/Store Name:	
*DEA #:	*Debit Memo #

DEA # is required; in order to process your form.

Address: _____

City: _____ State: _____ Zip: _____

Contact Name (please print): _____ Telephone #: _____

I have checked my stock and:

_____ I **do not** have stock of the recalled item(s) **OR** _____ I **do** have stock of the recalled item(s) listed above.

Anagrelide Capsules, USP 0.5 mg, 100 capsules/bottle		
NDC	**Lot**	**Quantity to Return Count Partials as 1**
0172-5241-60	GD01090	

Please send me _____ shipping box labels

NON DIRECT CUSTOMERS ONLY: Please complete the following:

Purchased From (Wholesaler name): _____ DEA #: _____

DEA # is required; in order to process your form.

City: _____ State: _____

Please promptly return this form by FAX to: 817-868-5362 or by E-mail at: rxrecalls@inmar.com or Mail to: Inmar, Attn: Recall Coordinator, Inmar, 635 Vine Street, Winston Salem, NC 27101.

Inmar/MedTurn Use Only:				
Scan	Labels	Store	Kit	D.B