Teva Issues Voluntary Nationwide Recall of One Lot of Anagrelide Capsules, USP 0.5 mg to the Consumer Level

Recall Information for Consumers/Patients/Caregivers

05/20/2022

Dear Valued Consumer/Patient/Caregiver:

At Teva, our first priority is to our customers and patients. We are committed to ensuring the safe and effective use of our products.

Teva Pharmaceuticals USA, Inc. wishes to advise you of an expansion of its voluntary recall of one lot of **Anagrelide Capsules, USP 0.5 mg** that was initiated on 05/11/2022 to the Retail Level. This voluntary recall has now been extended to the Consumer/User Level. The lot in this recall is given in the table below. No other lots are impacted.

NDC	Lot	Exp. Date	Size
0172-5241-60	GD01090	05/2022	100 Capsules/Bottle

Reason for Drug Product Recall:

This voluntary recall was initiated due to dissolution test failure detected during routine stability testing. Failed dissolution can result in a slower rate and extent of drug release leading to less anagrelide available in the body. 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. For seriously ill patients with elevated platelet counts, less available anagrelide 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. Teva's **Anagrelide Capsules, USP 0.5 mg,** are packed in bottles with 100 capsules. Teva distributed 4224 bottles nationwide to its direct wholesale, distributor, and retail customers from 07-30-2020 through 09-02-2020 under the label of Teva Pharmaceuticals USA, Inc.

Returning the Recalled Drug Product:

As a Consumer/Patient/Caregiver, your first course of action should be to consult with your pharmacist, healthcare provider or physician who can advise you about an alternative treatment prior to discontinuation of the medication. The adverse health consequences associated with stopping the medication may be higher than the potential risk of continuing anagrelide treatment for a short period of time.

Once your pharmacist, healthcare provider or physician has provided an alternate medication to treat the patient's condition, we request that you return any remaining product in your possession. Please contact Teva's product recall processor to obtain instructions and a kit for returning your medication: Inmar at: 866-431-5972 (Dedicated Phone Line) or email Inmar at rxrecalls@inmar.com. Inmar will provide the materials that you will need to return your medication, which will include a pre-paid mailer and instructions for your reimbursement.

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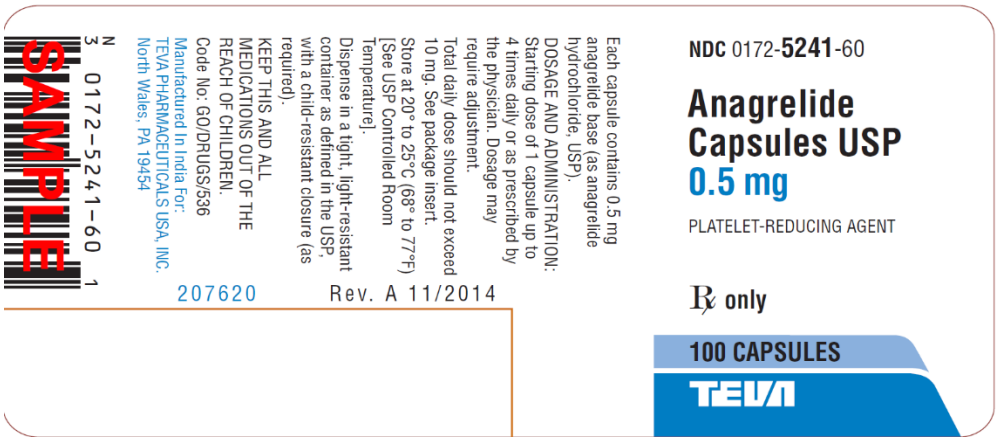
Please make sure you only return recalled product described in this letter. The cost of any drug products that are not the subject of this recall cannot be reimbursed.

Appearance of Anagrelide Capsules, USP 0.5 mg being recalled:

To help you identify whether you have the drug product that is the subject of the recall, description of its appearance and the product's labeling is below. Anagrelide Hydrochloride Capsules USP 0.5 mg are Gray and White capsules, which are imprinted with a "Hour Glass" Logo and 5241 on the grey portion and imprinted with 0.5 mg on the white portion of the capsule.

Product Labeling



Other Information:

If you wish to report an Adverse Event or a Product Quality Complaint, or if you have Medical Related Questions, please contact Teva's Medical Information at: : 888-838-2872, option 3, then, option 4. Live calls are received: Monday-Friday, 9:00 am - 5:00 pm Eastern Time and voicemail: 24 hrs/day, 7 days/week or by email at druginfo@tevapharm.com.

Adverse events or other problems experienced with the use of this product may also be reported to the FDA's MedWatch Adverse Event Reporting program online or by regular mail or fax.

- Complete and submit the report **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-1088.

Sincerely,

Regulatory Compliance, Teva Pharmaceuticals USA, Inc.