

Teva - Recall of anagrelide

- On May 20, 2022, <u>Teva announced</u> a consumer-level recall of one lot of <u>anagrelide</u> capsules due to dissolution test failure detected during routine stability testing.
- The recall was initially announced on May 11, 2022 as a retail-level recall and has now been extended to the consumer level.
 - Clinical Services will send notifications to members and their providers impacted by this recall.
 - The notifications provide information to help determine if the member's anagrelide is being recalled. Members with recalled product are advised to obtain a replacement from their pharmacy.
 - Anagrelide capsules that are not being recalled are available for patients to use.
- The impacted lot was distributed nationwide from 7/30/2020 through 9/02/2020.

| Product Description | NDC# | Lot# (Expiration Date) |
|----------------------------|--------------|------------------------|
| Anagrelide 0.5 mg capsules | 0172-5241-60 | GD01090 (5/2022) |

- Administration of recalled anagrelide 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 and clotting or bleeding events such as a heart attack or
 stroke, which could be life threatening.
- Anagrelide is 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.
- Patients should contact a pharmacist or health care provider for a replacement product. 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.
- Anyone with an existing inventory of the recalled product should stop distribution and quarantine the
 product immediately. Contact Inmar (appointed company for Teva) by phone at 1-866-431-5972 or by
 email at rxrecalls@inmar.com for return and refund information. Instructions for return and refund
 information are also provided a in consumer letter released by Teva.
- Patients should contact their physician or health care provider if they have experienced any problems that may be related to taking or using the recalled anagrelide.
- Contact Teva by phone at 1-888-838-2872 or by email at <u>druginfo@teva.com</u> for more information about the recall.



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