

Torrent Issues Voluntary Nationwide Recall of Anagrelide Capsules, USP Due to Dissolution Test Failure

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Torrent is voluntarily recalling one (1) lot of anagrelide capsules, USP to the consumer level due to dissolution test failure detected during routine quality testing.

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 could increase the risk of clotting or bleeding events such as a heart attack or stroke which could be life-threatening. To date, Torrent has not received any reports of adverse events related to this recall.

Anagrelide is used to treat a blood cell disorder called thrombocytopenia (also called thrombocytosis), which occurs when your body produces too many platelets.

As the risk of harm may be higher if the treatment is stopped immediately without any alternative treatment, patients should contact their pharmacist or physician who can advise them about an alternative treatment prior to returning their medication.

The product subjected to the recall is listed below and packaged in bottles. The product can be identified by checking the product name, manufacturer details, and batch or lot number on the bottle containing the product.

NDC	Manufacturer	Product Description	Lot/Batch	Expiration Date
13668-462-01	Torrent	anagrelide capsule USP 1 mg, 100-count bottles	BFD1G001	12/2021

Anagrelide capsules, USP were distributed nationwide to Torrent's wholesale distributor and retail customers. Torrent is notifying its distributors and customers by phone and in writing to immediately discontinue distribution of the specific lots being recalled and to notify their sub-accounts. Torrent is arranging for return of all recalled products to Qualanex. Instructions for returning recalled products are given in the recall letter.

Consumers with **medical questions regarding this recall or to report an adverse event** can contact Torrent at:

- 1-800-912-9561 (live calls received 8:00 am – 5:00 pm Eastern Time, Monday to Friday; voicemail available 8:00 am – 5:00 pm Eastern Time, Monday to Friday).
- Medinfo.Torrent@apcerls.com

Consumers should also contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product.

Any general **questions regarding the return of this product** should be directed to Qualanex at 1-888-424-4340 (live calls received 8 am - 5 pm Eastern Time, Monday to Friday).

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 United States (US) Food and Drug Administration.

Link to FDA recall notification: <https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/torrent-pharmaceuticals-limited-issues-voluntary-nationwide-recall-anagrelide-capsules-usp-due>

Company Contact Information

Consumers:

Torrent Pharmaceuticals Limited
1-800-912-9561
Medinfo.Torrent@apcerls.com

Product Photos

Click [here](#) for product photos.