

COMPANY ANNOUNCEMENT

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

When a company announces a recall, market withdrawal, or safety alert, the FDA posts the company's announcement as a public service. FDA does not endorse either the product or the company.

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Summary

Company Announcement Date:

December 09, 2020

FDA Publish Date:

December 09, 2020

Product Type:

Drugs

Reason for Announcement:

Due to dissolution test failure

Company Name:

Torrent Pharmaceuticals Limited

Brand Name:

Torrent Pharmaceuticals Limited

Product Description:

Anagrelide Capsule USP 1mg

Company Announcement

Torrent Pharmaceuticals Limited is voluntarily recalling one 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 (blood coagulation) and clotting or bleeding events such as a heart attack or stroke which could be life-threatening. To date, Torrent Pharmaceuticals Limited has not received any reports of adverse events related to this recall.

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

As the risk of harm to the patient's health 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 Pharmaceuticals LTD	Anagrelide Capsule USP 1mg,100-count bottles	BFD1G001	12/2021

Anagrelide Capsules, USP were distributed nationwide to Torrent's wholesale distributor and retail customers. Torrent Pharmaceuticals Limited 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 Pharmaceuticals Limited at:

- 1-800-912-9561 (live calls received 8:00 am – 5:00 pm Eastern Time (Monday-Friday), voicemail available 8:00 am – 5:00 pm Eastern Time (Monday-Friday)).
- Medinfo.Torrent@apcerls.com (mailto: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 - 5:00 pm Eastern Time, Monday-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 (</safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/reporting-serious-problems-fda>)
- Regular Mail or Fax: Download form (</safety/medical-product-safety-information/medwatch-forms-fda-safety-reporting>) 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 U.S. Food and Drug Administration.

Company Contact Information

Consumers:

Torrent Pharmaceuticals Limited

☎ 1-800-912-9561

✉ Medinfo.Torrent@apcerls.com (mailto:Medinfo.Torrent@apcerls.com)

Product Photos



100 Capsules NDC 13668-462-01

Rx only

Anagrelide Capsules, USP

1 mg

Platelet-reducing Agent

Each capsule contains 1 mg of anagrelide base (as anagrelide hydrochloride, USP).

DOSAGE AND ADMINISTRATION:
 The recommended starting dosage of Anagrelide is 0.5 mg 4 times a day or 1 mg twice a day, which should be maintained for at least one week. Dosage may require adjustment. Total daily dose should not exceed 10 mg. See package insert for complete information.

Keep this and all drugs out of the reach of children.

Store at 20° to 25°C (68° to 77°F); excursions permitted between 15°C and 30°C (59°F and 86°F) [see USP Controlled Room Temperature].

Dispense in a tight, light-resistant container with a child-resistant closure.

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 Pharmaceuticals
 Manufactured in India for:
 TORRENT PHARMACEUTICALS, Basking Ridge, NJ 07920.

Mfg. Lic. No.: Q526

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