RXADVANCE
136 Turnpike Rd
Southborough, MA 01772

Anagrelide Capsules Recall Alert

Date of Notice: 12/09/2020

Brief Description of Recall Alert

Torrent Pharmaceuticals Limited is voluntarily recalling one lot of anagrelide capsules, USP to the consumer level due to a 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.

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.

Affected Products

Drug Name & Strength	NDC	Lot	Expiration Date
anagrelide capsule USP 1mg, 100-count bottles	13668-462-01	BFD1G001	12/2021

Prescriber Information

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.

To date, Torrent Pharmaceuticals Limited has not received any reports of adverse events related to this recall.

Adverse reactions or issues experienced with the use of this drug 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

Member Information

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) or,
- 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 8:00 am - 5:00 pm Eastern Time, Monday-Friday).

RxAdvance Response

RxAdvance recommends that you speak to your doctor if they have experienced any issues that may be related to taking this drug.