

## **Anagrelide – Torrent Pharmaceuticals Limited**

On December 9, 2020, the U.S. Food and Drug Administration (FDA) announced that Torrent Pharmaceuticals Limited is voluntarily recalling one lot of Anagrelide Capsules 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.

<b>NDC</b>	<b>Manufacturer</b>	<b>Product Description</b>	<b>Lot/Batch</b>	<b>Expiration Date</b>
13668-462-01	Torrent Pharmaceuticals LTD	Anagrelide Capsule USP 1mg,100-count bottles	BFD1G001	12/2021

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.