December 10, 2020 **COM-2020-093**

RECALL NOTIFICATION

FDA PUBLICATION DATE: December 9, 2020

DRUG NAME: Anagrelide capsule, USP 1mg

COMPANY: Torrent Pharmaceuticals Limited

REASON: Dissolution test failure

Dear provider of pharmaceutical services,

PharmPix is committed to the health and wellness of our members. The clinical team wants to communicate the latest up-to-date information on drug safety. For this reason, we are notifying you that on December 9, 2020, the U.S. Food and Drug Administration (FDA) published a voluntary recall for one lot of **Anagrelide capsule USP 1mg** manufactured by Torrent Pharmaceuticals Limited.

NDC	Product description	Lot # / Batch	Expiration Date
13668-0462-01	**Anagrelide Capsule USP 1mg,100-count bottles**	BFD1G001	12/2021

The voluntary recall is due to dissolution test failure detected during quality testing. This situation could affect the pharmacological effect of the drug leading to an increased risk of clotting. Up to date, no adverse events have been reported to the manufacturer.

Pharmacy required actions(s):

- Identify if the product is in inventory and immediately stop dispensing it.
- Advise patients to contact their physician or healthcare provider for an alternative treatment and or experienced any problems related to using this drug product.

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Contact information:

- For medical questions or to report adverse drug event, 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

Remember, you can report adverse events or side effects at MedWatch: The FDA Safety Information and Adverse Event Reporting Program by any of the following ways:

- Complete and submit the MedWatch Online Voluntary Reporting Form online.
- Download FDA Form 3500 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.

Additional information can be found at:

- FDA Drug Recall web page: https://www.fda.gov/drugs/drug-safety-and-availability/drug-recalls

If you have any questions or wish to have more information regarding this document, you can call us at 787-522-5252, extension 137. In addition, know that you can access our recent communications at our providers' portal: https://www.pharmpix.com/providers/.

Regards,

PharmPix Clinical Department

Reference(s):

U.S. Food and Drug Administration. (2020). Torrent Pharmaceuticals Limited Issues Voluntary Nationwide Recall of Anagrelide Capsules, USP Due to Dissolution Test Failure. Retrieved on December 10, 2020 from: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/torrent-pharmaceuticals-limited-issues-voluntary-nationwide-recall-anagrelide-capsules-usp-due?utm_medium=email&utm_source=govdelivery