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

Date: 12/9/2020

At Magellan Rx Management, we want to help you get the best possible care. We have created a site to share drug recall information.

Torrent Pharmaceuticals has posted a lot recall of anagrelide capsules.

**About this Recall:**
Torrent is voluntarily recalling 1 lot of anagrelide capsules to the consumer level due to dissolution test failure detected during routine quality testing.

**What this means to you:**
Failed dissolution can result in a slower rate and amount of drug release leading to less anagrelide available in the body. For seriously ill patients with increased platelet counts, less available anagrelide could increase the risk for 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 thrombocythemia (also called thrombocytosis), which occurs when your body produces too many platelet cells.

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 before returning their medication.

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

<table>
<thead>
<tr>
<th>NDC</th>
<th>Manufacturer</th>
<th>Product Description</th>
<th>Lot/Batch</th>
<th>Expiration Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>13668-462-01</td>
<td>Torrent</td>
<td>anagrelide capsule, USP 1 mg 100-count bottles</td>
<td>BFD1G001</td>
<td>12/2021</td>
</tr>
</tbody>
</table>

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.

- Regular Mail or Fax: [Download form](https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home) 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 (FDA).


FDA contact information for reporting adverse events/quality complaints can be reached online at [https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home](https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home)

or by calling the FDA at 1-888-INFO-FDA (1-888-463-6332) and then select prompt #2.