



## Teva – Recall of paliperidone

- On June 15, 2017, the [FDA announced](#) a consumer-level recall of one lot of Teva's [paliperidone](#) 3 mg extended-release tablets due to failing test results for dissolution. Teva cannot at this time exclude the potential for additional tablets to be below specification.
  - The recalled tablets were distributed under the Actavis label.
  - This recall was initially classified as retail-level on May 31, 2017.
- The recalled lot was distributed from December 12, 2016 through March 16, 2017.

| Product Description  | NDC #        | Lot # (Expiration date) |
|--|--------------|-------------------------|
| Paliperidone 3 mg extended-release tablets, 90 count bottles | 0591-3693-19 | 1160682A<br>(6/2018)    |

- Paliperidone is indicated for the treatment of schizophrenia and for the treatment of schizoaffective disorder as monotherapy and an adjunct to mood stabilizers and/or antidepressant therapy.
- Taking a product for the treatment of schizophrenia and schizoaffective disorders that has failed dissolution could result in less drug being absorbed.
  - If a patient takes two or more consecutive dosing regimens with the recalled product, a failure to maintain therapeutic levels could occur.
  - This may reduce effectiveness in treating a patient's mental and/or mood symptoms, including suicidal thoughts and behavior, self-injurious behavior, mental hospitalizations, assaults, aggressive behavior, as well as vocal and motor tics.
- Based on Teva's investigation, the likelihood of consuming two or more consecutive doses with the recalled product is low. To date, no post marketing adverse events have been received for lack of effectiveness for this recalled lot.
- Anyone with an existing inventory of the recalled lot should stop use and distribution, and return all recalled product. Teva does not expect any paliperidone supply interruptions.
- Consumers with questions regarding this recall can contact Teva at **1-888-838-2872** or [druginfo@tevapharm.com](mailto:druginfo@tevapharm.com).
- Consumers should contact their healthcare provider, physician and/or pharmacist if they have experienced any problems that may be related to paliperidone.



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