Company Announcement

When a company announces a recall, market withdrawal, or safety alert, the FDA posts the company's announcement as a public service. FDA does not endorse either the product or the company.

Teva Pharmaceuticals, USA Extends Voluntary Nationwide Recall to Consumer/User Level for One Lot of Paliperidone Extended-Release Tablets, 3mg, 90 Count Bottles Distributed Under the Actavis Pharma Inc. Label Due to Dissolution Test Failure

For Immediate Release

June 15, 2017

Contact

Consumers

druginfo@tevapharm.com (mailto:druginfo@tevapharm.com)
1-888-838-2872

Media

Denise Bradley
denise.bradley@tevapharm.com (mailto:denise.bradley@tevapharm.com)
215-591-8974

Announcement

Teva Pharmaceuticals USA, Inc. (Teva) initiated a voluntary recall to retail-level on 05/31/2017 for one lot of Paliperidone Extended-Release Tablets, 3mg, 90 count bottles that was distributed under the Actavis Pharma Inc. label. In coordination with FDA, Teva is extending this recall to the CONSUMER/USER level.

This recall is being carried out due to failing test results for dissolution. Teva cannot at this time exclude the potential for additional tablets to be below specification.

Paliperidone Extended Release Tablets, 3mg is indicated for the treatment of schizophrenia and schizoaffective disorders and was distributed Nationwide in the USA to wholesalers.

Taking a product for the treatment of schizophrenia and schizoaffective disorders that has failed dissolution could result in less drug being absorbed. If two or more consecutive dosing regimens are with affected product, a failure to maintain therapeutic levels could occur, which could 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 affected product is low. In addition, no post marketing adverse events have been received to date for lack of effectiveness for this recalled lot.

The recalled lot is:

Lot #	Exp. Date	Strength	Bottle Size	NDC#	Dates Distributed	Quantity Sold
1160682A	6/2018	3mg	90 Count	0591-3693-19	12/12/2016 – 03/16/2017	360 Bottles

Teva has issued an Urgent Drug Recall Letter to its direct accounts. Teva has made arrangements for impacted product to be returned to Inmar. The letter asks these consignees to notify their customers that were shipped the recalled lot informing them of this recall. Anyone with an existing inventory of the recalled lot should stop use and distribution, and follow the instructions in the letter for product returns. Teva does not expect any supply interruptions.

Consumers with questions regarding this recall can contact Teva by 1-888-838-2872, option 3, then option 4, Monday – Friday (excluding holidays), 9 am to 5 pm Eastern Time, or email **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 this drug product.

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.

- Complete and submit the report **Online**: **www.fda.gov/medwatch/report.htm (http://www.fda.gov/medwatch/report.htm)**
- **Regular Mail or Fax:** Download form **www.fda.gov/MedWatch/getforms.htm (http://www.fda.gov/MedWatch/getforms.htm)** to request a reporting form, ten complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

Alternatively, consumers and healthcare professionals wishing to report adverse reactions experienced with the use of this product may call 1-888-838-2872, option 3, then option 4, Monday – Friday (excluding holidays), 9 am to 5 pm Eastern Time, or email **druginfo@tevapharm.com (mailto:druginfo@tevapharm.com)**.

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.

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Industry Guidance (/Safety/Recalls/IndustryGuidance/default.htm)

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