



NEWS RELEASE

Merck Recalls TEMODAR® and Temozolomide Bottles with Cracked Caps Due to Failure to Meet Child-Resistant Closure Requirement

8/18/2015

Patients Should Visually Examine Bottle Caps for Cracks and if Cracks are Found, Ensure the Bottles are Stored Out of the Reach of Children

Replacement Caps for Patients Are Available

Medication Within the Bottles Is Not Affected; Patients May Continue to Take Their Medicine as Prescribed

KENILWORTH, N.J.--(BUSINESS WIRE)--Merck (NYSE: MRK), known as MSD outside the United States and Canada, in conjunction with the U.S. Consumer Product Safety Commission (CPSC) today asked that all customers, including patients, inspect all bottles of TEMODAR® (temozolomide) capsules and all bottles of Temozolomide capsules (generic) for potential cracks in the child-resistant bottle caps. The medicine is manufactured by Merck and distributed in the United States by Merck as TEMODAR. The Temozolomide capsules (generic) are manufactured and packaged by Merck but sold and distributed by Sandoz, the authorized generic partner, under the Sandoz label. In addition to these supplies, Merck also provides TEMODAR in the United States in sachets (or pouches); TEMODAR in sachets are not affected.

Merck believes that approximately 1,100 bottles out of an estimated 276,000 distributed bottles of TEMODAR and Temozolomide capsules (generic) could potentially have cracked caps. Those bottles could be at wholesalers, pharmacies, healthcare providers or with patients. The bottle label will say it is provided by Merck & Co. or by Sandoz (for the generic). To see pictures of bottles, please visit www.merck.com and click on "Important Temodar

Information.”

Information for patients

All bottle caps of TEMODAR and Temozolomide capsules (generic) should be immediately inspected for cracks. If the cap has a crack, patients should immediately place the bottle out of the sight and reach of young children. A crack in the bottle cap could render the closure no longer child resistant. Patients wishing to obtain a replacement cap, have questions, or who need assistance, should call the Merck Information Center at 1-800-943-8069. Because the quality of the medication in the bottles is not affected, patients may continue to use the drug as directed.

Information for retailers, pharmacies, health care professional and wholesalers

Retailers, pharmacists and health care professional should also inspect caps for cracks. Any bottle with a cracked cap should not be distributed to patients. Wholesalers may return any bottles with cracked caps if they are observed. For questions, returns, or if assistance is needed, contact the Merck Information Center at 1-800-943-8069 from 8:00 am to 8:00 pm Eastern Time Monday through Friday.

“This recall does not relate to the quality or efficacy of the medicine, and patients can continue taking their medicine. The patients who use our medicines are our highest priority at Merck, and we apologize for any inconvenience this situation may cause our patients and customers,” said Michael Rosenblatt, M.D., executive vice president and chief medical officer for Merck. “We ask that anyone in possession of a bottle of TEMODAR or Temozolomide capsules inspect the bottle caps for cracks. If patients find cracks in the bottle cap, they can contact us for a replacement, but they also should immediately ensure that the medicine is out of sight and reach of children as should always be the case.”

TEMODAR and Temozolomide capsules (generic) are prescription medicines used to treat adults with certain brain cancer tumors.

About Merck

Today's Merck is a global health care leader working to help the world be well. Merck is known as MSD outside the United States and Canada. Through our prescription medicines, vaccines, biologic therapies, and animal health products, we work with customers and operate in more than 140 countries to deliver innovative health solutions. We also demonstrate our commitment to increasing access to health care through far-reaching policies, programs and partnerships. For more information, visit www.merck.com and connect with us on [Twitter](#), [Facebook](#) and [YouTube](#).

Forward-Looking Statement of Merck & Co., Inc., Kenilworth, N.J., USA

This news release of Merck & Co., Inc., Kenilworth, N.J., USA (the “company”) includes “forward-looking statements” within the meaning of the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995. These statements are based upon the current beliefs and expectations of the company’s management and are subject to significant risks and uncertainties. If underlying assumptions prove inaccurate or risks or uncertainties materialize, actual results may differ materially from those set forth in the forward-looking statements.

Risks and uncertainties include but are not limited to, general industry conditions and competition; general economic factors, including interest rate and currency exchange rate fluctuations; the impact of pharmaceutical industry regulation and health care legislation in the United States and internationally; global trends toward health care cost containment; technological advances, new products and patents attained by competitors; challenges inherent in new product development, including obtaining regulatory approval; the company’s ability to accurately predict future market conditions; manufacturing difficulties or delays; financial instability of international economies and sovereign risk; dependence on the effectiveness of the company’s patents and other protections for innovative products; and the exposure to litigation, including patent litigation, and/or regulatory actions.

The company undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise. Additional factors that could cause results to differ materially from those described in the forward-looking statements can be found in the company’s 2014 Annual Report on Form 10-K and the company’s other filings with the Securities and Exchange Commission (SEC) available at the SEC’s Internet site (www.sec.gov).

Merck

Media:

Pamela Eisele, 267-305-3558

or

Skip Irvine, 215-652-6059

or

Investors:

Justin Holko, 908-740-1879