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Antifungal Treatment Should Be Taken Off the Market, Public Citizen Tells FDA

Ketoconazole Offers No Unique Benefits, Only Unique Risks Compared With Other, Safer Antifungals, According to FDA's Own Experts

Note: This release and the petition refer only to the oral form of ketoconazole and not to other formulations, such as creams.

WASHINGTON, D.C. – The oral formulations of the antifungal medication ketoconazole should be removed from the market immediately because their questionable benefits are far outweighed by risks of severe liver injury and other side effects, Public Citizen said today in a petition to the U.S. Food and Drug Administration (FDA).

Ketoconazole was approved in 1981 to treat fungal infections; however, over the past three decades, evidence has mounted about the risks of the medication. In 1983, a black box warning was added to the label about fatal liver damage. In July 2013, the FDA issued a safety communication restricting the approved uses of ketoconazole to rare, serious fungal infections and mandated that a medication guide be distributed with each prescription to inform patients of ketoconazole's severe risks of liver injury, adrenal gland disorders and potentially dangerous medication interactions.

The same day as the FDA's announcement keeping ketoconazole on the U.S. market, a key committee of the European Medicines Agency (EMA, the European equivalent of the FDA) recommended that all forms of ketoconazole be removed from the European market because the agency had concluded that the risks outweighed its limited benefits for any fungal infection.

In addition, Public Citizen learned – after obtaining an unreleased, internal agency memo – that six months before the FDA's July 2013 announcement restricting ketoconazole, a team of FDA scientists at the Office of Surveillance and Epidemiology (OSE) reached the same conclusion as the EMA: that ketoconazole should be removed from the market.

The OSE team was "unable to view the risk of serious potentially life-threatening [liver] injury as tolerable for the potential benefit of ketoconazole treatment" for any use. Importantly, the OSE scientists noted that, for all of ketoconazole's remaining FDA-approved uses, multiple treatments exist that are safer and equally or more effective.

In 2014, the year after the FDA rescinded ketoconazole's most common uses ? for non-life threatening skin and nail infections ? 462,000 prescriptions were still dispensed for the medication, representing only a 24 percent decline from the 609,000 prescriptions dispensed in 2012.

Using data relied on by the OSE scientists in their analyses, Public Citizen conservatively estimated that approximately 600 cases of liver injury requiring hospitalization or a referral to a liver specialist may have resulted from the 462,000 prescriptions for ketoconazole used in the United States in 2014.

"The FDA's own experts concluded that ketoconazole was too dangerous to remain on the market – for any of its approved uses – yet the agency continues to allow hundreds of thousands of prescriptions for the medication to be filled each year, likely resulting in hundreds of preventable cases of serious liver damage," said Dr. Sammy Almashat, researcher with Public Citizen's Health Research Group. "The FDA needs to listen to its own scientists and follow the EMA's example in banning ketoconazole as an antifungal treatment."

Read the petition and the OSE reviewers' memo.

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OUR EXPERTS

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Media Contacts

Angela Bradbery, Director of Communications
w. (202) 588-7741
c. (202) 503-6768
abradbery@citizen.org, Twitter

Don Owens, Deputy Director of Communications
w. (202) 588-7767
dowens@citizen.org

Karilyn Gower, Press Officer
w. (202) 588-7779
kgower@citizen.org

David Rosen, Press Officer, Regulatory Affairs
w. (202) 588-7742
drosen@citizen.org

Nicholas Florko, Communications Officer, Global Trade Watch
w. (202) 454-5108
nflorko@citizen.org

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