

FDA OKs first generic version of daraprim, best known as the 'pharma bro' drug

March 2 2020



(HealthDay)—The first generic version of Daraprim (pyrimethamine)

tablets for the treatment of toxoplasmosis has been approved by the U.S. Food and Drug Administration.

"Today's approval is especially important for populations that are more susceptible to toxoplasmosis infections, such as [pregnant women](#) and individuals with HIV or AIDS, by paving the way for more choices in treatment options," FDA Commissioner Dr. Stephen Hahn said in an agency news release.

Daraprim first gained notoriety in 2015 when its maker, Turing Pharmaceuticals, jacked up the price of the drug by 5,000%, from \$13.50 a pill to \$750 a pill, *CNN* reported.

Martin Shkreli, who was the company's CEO at the time, became known by the moniker "pharma bro," according to *CNN*.

The new generic version of the medication is approved for use with a sulfonamide, which are a group of medicines used to treat bacterial infections.

Toxoplasmosis is an infection caused by a parasite called *Toxoplasma gondii*, which can be contracted by: eating undercooked, contaminated meat or shellfish; drinking water contaminated with the parasite; or accidentally swallowing the parasite through contact with cat feces that contain it.

Severe cases can cause damage to the brain, eyes or other organs. Toxoplasmosis is the leading cause of foodborne illness-related death in the United States, according to the FDA.

Severe toxoplasmosis is more likely in pregnant women and people with weak immune systems, such as those with HIV or AIDS, those taking certain types of chemotherapy and those who have recently received an

[organ transplant](#).

However, even some people with healthy immune systems may suffer eye damage from toxoplasmosis.

The newly approved generic version of pyrimethamine tablet is made by Cerovene Inc.

"Through the FDA's Drug Competition Action Plan, we've worked to remove barriers in generic drug development by not only taking actions that improve the efficiency of the development, review and approval of generic drugs, but also by closing loopholes that allow brand-name [drug](#) companies to 'game' the rules in ways that delay generic competition that Congress intended," Hahn said.

"These important efforts include improving access to safe, effective and high-quality generic medications," he said.

More information: The U.S. Centers for Disease Control and Prevention has more on [toxoplasmosis](#).

Copyright © 2020 [HealthDay](#). All rights reserved.

Citation: FDA OKs first generic version of daraprim, best known as the 'pharma bro' drug (2020, March 2) retrieved 19 September 2024 from <https://medicalxpress.com/news/2020-03-fda-oks-version-daraprim-pharma.html>

<p>This document is subject to copyright. Apart from any fair dealing for the purpose of private study or research, no part may be reproduced without the written permission. The content is provided for information purposes only.</p>
--