

First generic versions of Singulair approved

August 4 2012

(HealthDay) -- The first generic versions of Singulair (montelukast sodium) have been approved by the U.S. Food and Drug Administration.

The product is not meant to treat sudden onset of serious [asthma symptoms](#), the FDA warned, but it does treat asthma and hay fever symptoms by blocking substances in the body called leukotrienes, the agency said Friday in a news release.

The FDA said the product could cause serious side effects, including behavioral or mood changes, depression, hallucinations, [upper respiratory infection](#), or feeling numbness in the extremities. Anyone who has these symptoms should immediately see a physician, the agency said.

Less serious but more common adverse reactions could include: fever, headache, sore throat, cough, stomach pain, diarrhea, ear ache or runny nose.

Approval to produce generic tablets, generic chewable tablets or both versions was granted to: Apotex Inc., Aurobindo Pharma, Endo Pharmaceuticals, Glenmark Generics, Kudco Ireland Inc., Mylan Inc., Roxane Laboratories, Sandoz Inc., Teva [Pharmaceuticals Inc.](#), and Torrent Pharmaceuticals, the FDA said.

The agency stressed the generic drugs it approves are equal in strength and quality to their brand-name counterparts.

Brand-name Singulair, made by Merck & Co., was approved by the FDA in 1998.

More information: Medline Plus has more about [this drug](#).

Copyright © 2012 [HealthDay](#). All rights reserved.

Citation: First generic versions of singulair approved (2012, August 4) retrieved 27 April 2024 from <https://medicalxpress.com/news/2012-08-versions-singulair.html>

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.