

FDA News

FOR IMMEDIATE RELEASE

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FDA Approves First Generic Versions of Trileptal®

The U.S. Food and Drug Administration today approved the first generic versions of Trileptal® (oxcarbazepine), an anticonvulsant drug. Generic oxcarbazepine is FDA-approved for use alone or in combination with other medications in the treatment of partial seizures in adults and children aged four years and above.

"FDA requires generic drugs to have the same quality, strength, purity and stability as brand-name drugs," said Gary J. Buehler, director of FDA's Office of Generic Drugs. "The agency ensures that generic drugs are safe and effective, offering alternatives to Americans in choosing their prescription drugs."

Oxcarbazepine tablets in three strengths (150 milligrams, 300 milligrams and 600 milligrams) are manufactured by Roxane Laboratories Inc., Glenmark Pharmaceuticals Limited, and Sun Pharmaceutical Industries Limited.

The labeling of the generic products may differ from that of Trileptal® because parts of the Trileptal® labeling are protected by patents and/or exclusivity.

According to the publication *Drug Topics*, Trileptal® was 74th best selling brand-name drug in by retail dollars in the United States in 2006.

Serious skin reactions have been reported in children and adults in association with Trileptal® use. In the event a skin reaction should occur while taking Trileptal® patients should immediately consult with their health care provider. Common side effects reported with Trileptal® use include dizziness and drowsiness.

For information:

FDA Generic Initiative for Value and Efficiency
www.fda.gov/oc/initiatives/advance/generics.html

FDA's Office of Generic Drugs
www.fda.gov/cder/ogd/

Frequently asked questions about generic drugs
www.fda.gov/cder/consumerinfo/generics_q&a.htm