ProCare Rx

URGENT NOTICE

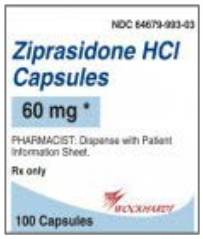
TYPE: DRUG SAFETY COMMUNICATION

Rare but Potentially Fatal Skin Reactions

Drug Name: **Ziprasidone** (Marketed as Geodon and Generics)

Audience: Psychiatry, Dermatology, Pharmacy, Family Practice

Date: **12/11/2014**



ISSUE

FDA is warning that the antipsychotic drug ziprasidone (marketed under the brand name, Geodon, and its generics) is associated with a rare but serious skin reaction that can progress to affect other parts of the body. A new warning has been added to the Geodon drug label to describe the serious condition known as drug reaction with Eosinophilia and Systemic Symptoms (DRESS). See the FDA Drug Safety Communication for a data summary and additional information.

DRESS may start as a rash that can spread to all parts of the body. It can include fever, swollen lymph nodes, and inflammation of organs such as the liver, kidney, lungs, heart, or pancreas. DRESS also causes a higher-than-normal number of a particular type of white blood cell called eosinophils in the blood. DRESS can lead to death.

BACKGROUND

Ziprasidone is an atypical antipsychotic drug used to treat schizophrenia and bipolar I disorder.

FDA reviewed information from six patients in whom the signs and symptoms of DRESS appeared between 11 and 30 days after ziprasidone treatment was started. None of these patients died (see data summary in the FDA Drug Safety Communication). Based on this information, FDA required the manufacturer of Geodon to add a new warning for DRESS to the Warnings and Precautions section of the drug labels for the capsule, oral suspension, and injection formulations.

RECOMMENDATION

Patients who have a fever with a rash and/or swollen lymph glands should seek urgent medical care. Health care professionals should immediately stop treatment with ziprasidone if DRESS is suspected.

Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report Online: *www.fda.gov/MedWatch/report.htm*
- Download form or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178