AMERICAN HEALTH CARE

DRUG PRODUCTS & SAFETY NEWS

Olanzapine Safety Communication

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The U.S. Food and Drug Administration (FDA) is warning that the antipsychotic medicine, olanzapine, can cause a rare but serious skin reaction that can progress to affect other parts of the body. Olanzapine is an antipsychotic medicine used to treat mental health disorders schizophrenia and bipolar disorder. It can decrease hallucinations, in which people hear or see things that do not exist, and other psychotic symptoms such as disorganized thinking. Olanzapine is available under the brand names Zyprexa, Zyprexa Zydis, Zyprexa Relprevv, and Symbyax, and also as generics.

The FDA is adding a new warning to the drug labels for all olanzapine-containing products that describes this severe condition known as Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS). DRESS may start as a rash that can spread to all parts of the body. It can include fever and swollen lymph nodes and a swollen face. It causes a higher-than-normal number of infection-fighting white blood cells called eosinophils that can cause inflammation, or swelling. DRESS can result in injury to organs including the liver, kidneys, lungs, heart, or pancreas, and can lead to death.

Patients taking olanzapine-containing products who develop a fever with a rash and swollen lymph glands, or swelling in the face, should seek medical care right away. The combined symptoms together are commonly seen in DRESS. Patients should talk with their health care professional about any questions or concerns. Patients should not stop taking olanzapine or change their dose without first talking with their health care professional. Sudden stopping of the medicine can be harmful without a health care professional's direct supervision.

Health care professionals should immediately stop treatment with olanzapine if DRESS is suspected. When prescribing the medicine, health care professionals should explain the signs and symptoms of severe skin reactions to patients and tell them when to seek immediate medical care.

Healthcare professionals and patients are encouraged to report any adverse events or side effects related to the use of this product and/or quality problems to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- ✓Complete and submit the report online: www.fda.gov/MedWatch/report.htm
- ✓Complete and return a form by mail (address on the pre-addressed form) or fax (1-800-FDA-0178).

[Call 1-800-332-1088 to request a reporting form or download a form at http://www.fda.gov/Safety/MedWatch/HowToReport/DownloadForms/default.htm.]

Source: http://www.fda.gov/Drugs/DrugSafety/ucm499441.htm