



**Olanzapine: Drug Safety Communication –  
FDA Warns About Rare But Serious Skin Reactions  
Including Zyprexa, Zyprexa Zydis, Zyprexa Relprevv, and Symbyax**

[Posted 05/10/2016]

FDA 發布藥物安全警訊，抗精神病藥物 Olanzapine 可能會造成罕見但嚴重的皮膚反應，隨後可能會影響身體的其他部位。FDA 將新增嚴重皮膚反應，即『伴隨嗜伊紅性白血球增加與全身症狀的藥物反應』Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS)之警訊於所有含 Olanzapine 成分的藥品仿單上。DRESS 開始時可能只是皮疹，但會逐漸擴展到身體的其他部位，同時包括發燒、淋巴結腫大、臉部浮腫和嗜伊紅性白血球的增加而導致發炎或腫脹，DRESS 也會造成器官的損傷，包括肝臟、腎臟、肺臟、心臟或胰臟等器官的侵犯而造成死亡，DRESS 是潛在的致命藥物反應，死亡率高達 10%。

**建議：**

DRESS 通常以合併症狀發病，病患如果服用含 Olanzapine 成分的藥物，發現有發燒伴隨起疹，同時淋巴腺腫大或者臉部浮腫時，應該立即就醫。如果有任何問題應該詢問專業的醫療人員，病患不應該在沒有告知醫療人員的情況下自行減低劑量或停藥。

醫療人員一旦懷疑是 Olanzapine 造成 DRESS 嚴重皮膚不良反應時，應立即停止使用藥物。

針對 DRESS 嚴重皮膚反應目前沒有特定的處置方式，最重要的是及早確認 DRESS 的症狀，將可能引發 DRESS 的藥物停用，支持性治療。如果廣泛的器官受到侵犯，可以考慮使用全身性皮質類固醇做治療。當開立 Olanzapine 時，醫療人員應向病人解釋嚴重皮膚反應的症狀，同時也包括尋求醫療協助的最佳時機。

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**AUDIENCE:** Psychiatry, Dermatology, Patient

**ISSUE:** 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. 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).

A search of the FDA Adverse Event Reporting System (FAERS) database identified 23 cases of DRESS reported with olanzapine worldwide since 1996, when the first olanzapine-containing product was approved.

FAERS includes only reports submitted to FDA, so there are likely to be additional cases about which FDA is unaware. One patient taking olanzapine experienced DRESS and died; however, this patient was taking multiple medicines that could also have contributed to death (see the Data Summary section of the Drug Safety Communication for more information).

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. DRESS is a potentially fatal drug reaction with a mortality rate of up to 10%.

**BACKGROUND:** 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.

**RECOMMENDATIONS:** 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. Talk with your health care professional about any questions or concerns. Do not stop taking olanzapine or change your dose without first talking with your health care professional. Sudden stopping of the medicine can be harmful without your health care professional's direct supervision.

Health care professionals should immediately stop treatment with olanzapine if DRESS is suspected. There is currently no specific treatment for DRESS. The important ways to manage DRESS are early recognition of the syndrome, discontinuation of the offending agent as soon as possible, and supportive care. Treatment with systemic corticosteroids should be considered in cases with extensive organ involvement. When prescribing the medicine, explain the signs and symptoms of severe skin reactions to your patients and tell them when to seek immediate medical care.