



**FDA Drug Safety Communication: FDA reporting mental health drug ziprasidone (Geodon)
associated with rare but potentially fatal skin reactions**

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FDA 提出警示，抗精神病藥物 ziprasidone 可能引發罕見但嚴重的皮膚不良反應，此類皮膚不良反應稱為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，簡稱 DRESS)。FDA 目前共接獲 6 名服用 ziprasidone 期間出現 DRESS 不良反應的個案，FDA 已要求將此不良反應加註於 ziprasidone 藥品仿單中。DRESS 不良反應初期症狀與皮疹相似，但會進展到身體其他部位，造成血液中嗜伊紅性白血球(eosinophils)升高、發燒、淋巴結腫大與肝、腎、心、肺、胰臟等器官的發炎，症狀嚴重者可能導致死亡。

建議

FDA 建議，民眾在服用 ziprasidone 期間若出現發燒合併皮疹症狀，或是出現淋巴結腫大現象，須立刻告知醫療人員。FDA 建議醫療人員，若發現患者在使用 ziprasidone 期間發生疑似為伴隨嗜伊紅性白血球增加與全身症狀的藥物反應，須立即停用 ziprasidone。

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AUDIENCE: Psychiatry, Dermatology, Pharmacy, Family Practice

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. 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.