MEDWATCH The FDA Safety Information and Adverse Event Reporting Program

Noxafil (posaconazole): Drug Safety Communication - Dosing Errors when Switching between Different Oral Formulations; Label Changes Approved

[Posted 01/04/2016]

FDA 警告抗黴菌藥物 Noxafil (posaconazole)兩種不同口服劑型的給藥劑量不同，已經有發生給藥劑量錯誤的案例。為了預防再次發生處方開立錯誤，仿單已經修訂，兩種不同劑型的藥物，給藥劑量不能直接做取代，而是需要做劑量上的調整。兩種不同劑型的藥物劑量，如果直接毫克數與相同毫克數的轉換是會造成藥物濃度高於或低於有效治療劑量。

自從 2013 年 11 月，Noxafil 的延遲釋放錠劑核准後，FDA 已經接到 11 件處方開立錯誤劑量給病人的案例，其中有一個案例造成病患死亡，也有一個導致病人入院。根據這些通報的案例，發現是因為醫療人員不知道 Noxafil (posaconazole)兩種不同的口服劑型的給藥劑量不能直接做取代，因其藥物動力學不一樣，故需要做劑量調整。

除了改變藥物的外包裝，廠商也修訂了仿單上給藥劑量和病患衛教的資訊，提醒病患和他們的醫療人員，兩者口服劑型的給藥劑量無法直接做取代。

建議

開立 Noxafil (posaconazole)時，處方應該明確說明藥物開立的劑型、給藥劑量和給藥頻率。病患也應該在轉換不同口服劑型前告知醫療人員。

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AUDIENCE: Internal Medicine, Infectious Disease

ISSUE: The FDA is cautioning that differences in dosing regimens between the two oral formulations of the antifungal Noxafil (posaconazole) have resulted in dosing errors. To help prevent additional medication errors, the drug labels were revised to indicate that the two oral formulations cannot be directly substituted for each other but require a change in dose. Direct mg for mg substitution of the two formulations can result in drug levels that are lower or higher than needed to effectively treat certain fungal infections.

Since the approval of Noxafil delayed-release tablets in November 2013, FDA received eleven reports of the wrong oral formulations being prescribed and/or dispensed to patients. One case resulted in death, and an additional case resulted in hospitalization. According to the reports, these outcomes were a result of health care professionals not knowing that the two oral formulations cannot be substituted for each other without adjusting the dose due to differences in how the medicine is absorbed and handled by the body.

In addition to changes to the outer carton of Noxafil (see Photos in Drug Safety Communication), its manufacturer Merck revised the prescribing information and the patient information in the drug label to alert patients and their health care professionals that the two oral formulations of Noxafil cannot be substituted for each other.

BACKGROUND: Noxafil is approved in two oral formulations: an oral suspension and a delayed-release tablet. It is also approved as an intravenous solution for injection. Noxafil is used to help prevent certain invasive fungal infections caused by fungi called Aspergillus and Candida. Noxafil is used in patients who have an increased chance of getting these infections due to weakened immune systems. Noxafil oral suspension is also used to treat a fungal infection called thrush caused by Candida in the mouth or throat area.

RECOMMENDATION: Prescribers should specify the dosage form, strength, and frequency on all prescriptions they write for Noxafil. Pharmacists should request clarification from prescribers when the dosage form, strength, or frequency is not specified. Patients should talk to their health care professional before they switch from one oral formulation to the other.