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Drugs

FDA advises against using oral ketoconazole in drug interaction studies due to serious potential side effects

[10/16/2013] The U.S. Food and Drug Administration (FDA) recommends that drug companies and researchers avoid using oral ketoconazole in drug interaction studies. Serious potential liver injury and adrenal gland problems make using the drug risky, and other strong CYP3A inhibitors are available that can be used as alternatives in drug interaction studies.

On July 25, 2013, FDA limited the use of Nizoral (ketoconazole) oral tablets to patients who do not have the option of taking alternative antifungals and who are undergoing treatment for certain fungal infections known as endemic mycoses (see Drug Safety Communication[1]). We took this action because oral ketoconazole can cause severe liver injuries and adrenal gland problems and may lead to harmful interactions with other drugs.

Oral ketoconazole has sometimes been used as a strong CYP3A inhibitor in drug interaction studies designed to predict the effect of other CYP3A inhibitors on a drug that is being studied. The information gained from such studies helps determine whether a health care professional needs to take a specific safety-related action when prescribing a drug in conjunction with a CYP3A inhibitor.

Most ketoconazole drug interaction studies are conducted in healthy subjects. In view of serious potential side effects associated with the drug, we recommend against the exposure of study subjects to ketoconazole. The dose of oral ketoconazole typically used in drug interaction studies (200-400 mg as a single dose or daily for as many as 5 days) is within the range of doses associated with liver injury. Instead of ketoconazole, FDA recommends that clarithromycin or itraconazole be used as the strong CYP3A inhibitor in drug interaction studies However, investigators can suggest other strong CYP3A inhibitors.

Related Information

- FDA Drug Safety Communication: FDA limits usage of Nizoral (ketoconazole) oral tablets due to potentially fatal liver injury and risk of drug interactions and adrenal gland problems[2]

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