From:	Board of Pharmacy
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Subject:	FDA MedWatch - Nizoral (ketoconazole) Oral Tablets: Drug Safety Communication - Prescribing for Unapproved Uses including Skin and Nail Infections Continues; Linked to Patient Death
Date:	Thursday, May 19, 2016 4:13:09 PM

Nizoral (ketoconazole) Oral Tablets: Drug Safety Communication - Prescribing for Unapproved Uses including Skin and Nail Infections Continues; Linked to Patient Death

AUDIENCE: Dermatology, Family Practice, Pharmacy, Patient

ISSUE: FDA is warning health care professionals to avoid prescribing the antifungal medicine ketoconazole oral tablets to treat skin and nail fungal infections. Use of this medication carries the risk of serious liver damage, adrenal gland problems, and harmful interactions with other medicines that outweigh its benefit in treating these conditions, which are not approved uses of the drug.

FDA approved label changes for oral ketoconazole tablets in 2013 to reflect these serious risks and to remove the indications for treatment of skin and nail fungal infections. However, an FDA safety review found that oral ketoconazole continues to be prescribed for these types of conditions. Since the 2013 labeling change, one patient death has been reported to the FDA due to liver failure associated with oral ketoconazole prescribed to treat a fungal infection of the nails. See the full Drug Safety Communication for further information.

BACKGROUND: Ketoconazole in tablet form is indicated to treat serious infections caused by fungi and should be used only when other effective therapy is not available or tolerated. It works by killing the fungus or preventing it from growing. The topical forms of ketoconazole that are applied to the skin or nails have not been associated with liver damage, adrenal problems, or drug interactions.

In a July 2013 Drug Safety Communication, FDA warned that ketoconazole tablets should not be used as a first-line treatment for any fungal infection because it can cause severe liver injury and adrenal gland problems, and advised it can lead to harmful interactions with other medicines. FDA determined that the risks outweigh the benefits for treating skin and nail fungal infections and approved label changes removing this indication from the drug label and limited its labeled indication to treating only serious fungal infections.

RECOMMENDATION: Health care professionals should use ketoconazole tablets only to treat serious fungal infections when no other antifungal therapies are available. Skin and nail fungal infections in otherwise healthy persons are not life-threatening, and so the risks associated with oral ketoconazole outweigh the benefits. Other treatment options are available over-the-counter and by prescription, but are also associated with risks that should be weighed against their benefits.

Patients should discuss with their health care professionals the risks and benefits of available therapies before using any medicine to treat skin and nail fungal infections. Patients taking ketoconazole tablets should seek medical attention right away if they experience any of these signs and symptoms of liver problems, which include loss of appetite, nausea, vomiting, or abdominal discomfort; yellowing of the skin or the whites of the eyes (jaundice); unusual darkening of the urine or lightening of the stools; or pain and discomfort in the right upper abdomen where the liver is located.

Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:
• Complete and submit the report Online: www.fda.gov/MedWatch/report
•Download form or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178.

View the MedWatch Safety Alert, including a link to the Drug Safety Communication, at:
http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm502073.htm