FDA updates oral nizoral label to reflect safety concerns

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(HealthDay)—The U.S. Food and Drug Administration has approved label changes for Nizoral (ketoconazole) oral tablets and added a Medication Guide detailing various associated safety concerns.

Nizoral tablets can cause liver injury, potentially necessitating transplantation or resulting in death. The Boxed Warning has been revised to include a strong recommendation against its use in patients with liver disease, and new recommendations for assessing and monitoring for liver damage. Nizoral can cause adrenal insufficiency by decreasing production of corticosteroids; health care professionals should monitor adrenal function in patients taking Nizoral who have existing adrenal problems or who are under prolonged periods of stress. The precautions section of the drug label has been updated to include information of potential drug interactions. The FDA has also approved a

Medication Guide with information on the potential risks linked with oral Nizoral use. Topical formulations of Nizoral have not been associated with liver damage, adrenal problems, and drug interactions.

Oral Nizoral tablets should no longer be a first-line treatment for any fungal infection, and should only be used for endemic mycoses when alternative antifungal therapies are unavailable or not tolerated. Use of Nizoral tablets should be limited by removing indications where the risks outweigh the benefits of treatment.

"[We] will continue to evaluate the safety of Nizoral tablets and will communicate with the public again if additional information becomes available," according to the FDA.

More information: More Information