

Nizoral Safety Communication

May 19, 2016

The U.S. Food and Drug Administration (FDA) is warning health care professionals to avoid prescribing the antifungal medicine Nizoral (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.

The 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, a safety review found that oral ketoconazole continues to be prescribed for these types of conditions.

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 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. 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.

Healthcare professionals and patients are encouraged to report any adverse events or side effects related to the use of this product and/or quality problems to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- ✓ Complete and submit the report online: www.fda.gov/MedWatch/report.htm
- ✓ Complete and return a form by mail (address on the pre-addressed form) or fax (1-800-FDA-0178).

[Call 1-800-332-1088 to request a reporting form or download a form at
<http://www.fda.gov/Safety/MedWatch/HowToReport/DownloadForms/default.htm>.]

Source: <http://www.fda.gov/Drugs/DrugSafety/ucm500597.htm>