From: General Board of Pharmacy Subscriber List on behalf of Board of Pharmacy
To: PHARM-GENERAL@DCALISTS.CA.GOV
Subject: Drug Information Update- New FDA Drug Safety Communication on Noxafil (posaconazole)
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The U.S. Food and Drug Administration (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.

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.

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.

Our review of the FDA Adverse Event Reporting System (FAERS) database identified cases of dosing errors with Noxafil. Noxafil was approved in 2006 as an oral suspension formulation. 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.

For more information, please visit: Noxafil.