Noxafil® (posaconazole) – Safety Communication

- On January 4, 2016, the FDA announced that differences in dosing regimens between the two oral formulations of the antifungal Noxafil (posaconazole) have resulted in dosing errors.
  - 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.
- Noxafil is available in two oral formulations: a delayed-release tablet and a suspension. It is also available in an injectable formulation.
  - The delayed-release tablet has a higher bioavailability than the oral suspension.
- Noxafil is an antifungal agent used to prevent certain fungal infections caused by Aspergillus and Candida. Noxafil oral suspension is also used to treat the fungal infection thrush that is caused by Candida in the mouth or throat area.
- Since the approval of Noxafil delayed-release tablets in November 2013, the FDA received 11 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.
- Merck, the manufacturer of Noxafil, has changed the outer cartons of both oral formulations and revised the prescribing information and the patient information in the drug label to alert patients and their healthcare professionals that the two oral formulations of Noxafil cannot be substituted for each other.

- FDA recommendations for healthcare providers:
  - 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.
- FDA recommendations for patients:
  - Patients should talk to their healthcare professional before they switch from one Noxafil oral formulation to the other.