Noxafil® PowderMix, Noxafil® (posaconazole) – New formulation approval, expanded indication

- On May 31, 2021, the FDA approved Merck's Noxafil PowderMix delayed-release oral suspension, for the prophylaxis of invasive *Aspergillus* and *Candida* infections in pediatric patients 2 years of age and older (who weigh 40 kg or less) who are at high risk of developing these infections due to being severely immunocompromised, such as hematopoietic stem cell transplant (HSCT) recipients with graft-versus-host disease (GVHD) or those with hematologic malignancies with prolonged neutropenia from chemotherapy.

- Noxafil was previously available as an injection, delayed-release tablet, and oral suspension.

    — Noxafil injection and delayed-release tablets share the same indication as the PowderMix formulation but in adults and pediatric patients 2 years and older. Noxafil injection was previously approved in patients 18 years of age and older. Noxafil delayed-release tablets were previously approved in patients 13 years of age and older. Noxafil oral suspension is approved for this indication in adults and pediatric patients 13 years of age and older.
    — Noxafil oral suspension is also approved for treatment of oropharyngeal candidiasis, including oropharyngeal candidiasis refractory to itraconazole and/or fluconazole.

- Noxafil PowderMix is contraindicated in patients with known or suspected hereditary fructose intolerance.

- The recommended dosing for Noxafil PowderMix in pediatric patients is based on weight.

Weight (kg)	Loading Dose (volume)	Maintenance Dose (volume)
10 to less than 12	90 mg twice daily on the first day	90 mg once daily
12 to less than 17	120 mg twice daily on the first day	120 mg once daily
17 to less than 21	150 mg twice daily on the first day	150 mg once daily
21 to less than 26	180 mg twice daily on the first day	180 mg once daily
26 to less than 36	210 mg twice daily on the first day	210 mg once daily
36 to 40	240 mg twice daily on the first day	240 mg once daily

- Noxafil oral suspension is not substitutable with Noxafil delayed-release tablets or Noxafil PowderMix for delayed-release oral suspension due to the differences in the dosing of each formulation. Therefore, the specific dosage recommendations for each of the formulations should be followed.

- Refer to the Noxafil/Noxafil PowderMix drug label for additional dosing and administration recommendations.

- Merck's launch plans for Noxafil PowderMix are pending. Noxafil PowderMix will be available as a 300 mg delayed-release oral suspension.