

Power and safety in an oral suspension¹



Indications and dosing for NOXAFIL® Oral Suspension¹

Indication	Dose and duration of therapy
Prophylaxis of invasive <i>Aspergillus</i> and <i>Candida</i> infections in patients, 13 years of age and older, 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	200 mg (5 mL) 3 times a day. The duration of therapy is based on recovery from neutropenia or immunosuppression
Treatment of oropharyngeal candidiasis (OPC)	Loading dose of 100 mg (2.5 mL) twice a day on the first day, then 100 mg (2.5 mL) once a day for 13 days
Treatment of OPC refractory to itraconazole and/or fluconazole	400 mg (10 mL) twice a day. Duration of therapy should be based on the severity of the patient's underlying disease and clinical response

Dosage and administration¹

- Each dose of NOXAFIL® should be administered with a full meal or with a liquid nutritional supplement in patients who cannot eat a full meal
- For patients who cannot eat a full meal or tolerate an oral nutritional supplement, alternative antifungal therapy should be considered or patients should be monitored closely for breakthrough fungal infections
- No reconstitution or refrigeration needed

Special Populations	Recommended Action
Patients with renal impairment	No dosage adjustment required. Due to the variability in exposure, patients with severe renal impairment should be monitored closely for breakthrough invasive fungal infections (IFIs)
Patients with severe diarrhea or vomiting	Monitor closely for breakthrough fungal infections
Patients with hepatic impairment	NOXAFIL® should be used with caution in patients with hepatic impairment. Discontinuation of NOXAFIL® must be considered in patients who experience symptoms consistent with liver disease that may be attributable to NOXAFIL®

Please see Important Safety Information on reverse page.

Please see enclosed full Prescribing Information.



Important Safety Information

NOXAFIL® has been shown to interact with several medications, including drugs that suppress the immune system, and these reactions may be serious. The product label should be consulted when other drugs are prescribed with NOXAFIL®.

Coadministration with sirolimus or ergot alkaloids is contraindicated. Coadministration with the CYP3A4 substrates terfenadine, astemizole, cisapride, pimozone, halofantrine, or quinidine, is also contraindicated since this may result in increased plasma concentrations of these medicinal products, leading to QTc prolongation and rare occurrences of torsades de pointes.

Serious and rare fatal toxicity from cyclosporine has occurred when taken in combination with NOXAFIL® and therefore reduction of the dose of drugs like cyclosporine or tacrolimus and frequent monitoring of drug levels of these medications are necessary when taking them in combination with NOXAFIL®.

In clinical trials, there were infrequent cases of hepatic reactions (eg, mild to moderate elevations in ALT, AST, alkaline phosphatase, total bilirubin, and/or clinical hepatitis). Rarely, more severe hepatic reactions including cholestasis or hepatic failure including fatalities were reported in patients with serious underlying medical conditions (eg, hematologic malignancies) during treatment with posaconazole. Liver function tests should be monitored at the start of and during the course of therapy. Discontinuation of NOXAFIL® must be considered in patients who experience symptoms consistent with liver disease that may be attributable to NOXAFIL®.

The safety and effectiveness of NOXAFIL® in patients below the age of 13 years old have not been established.

The most common treatment-related serious adverse events (1% each) in the combined prophylaxis studies were bilirubinemia, increased hepatic enzymes, hepatocellular damage, nausea, and vomiting.

In the pooled prophylaxis safety analysis, fever, headache, anemia, diarrhea, nausea, vomiting, abdominal pain, hypokalemia, and thrombocytopenia were frequently reported treatment-emergent adverse events.

In clinical studies of OPC and refractory OPC, adverse events were reported more frequently in the pool of patients with refractory OPC. The most commonly reported serious adverse events in refractory OPC patients included fever (13%) and neutropenia (10%).

Reference: 1. NOXAFIL® (posaconazole) Prescribing Information. Schering Corporation; Kenilworth, NJ; June 2008.

 Schering-Plough

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