



# National Clinical Practice Guidelines Recommend NOXAFIL® Antifungal Prophylaxis for High-Risk Cancer Patients<sup>1,2</sup>

## Treatment of Aspergillosis: Clinical Practice Guidelines of the Infectious Diseases Society of America (IDSA)<sup>1</sup>

RISK STATUS	CONDITION	PROPHYLAXIS AGAINST INVASIVE ASPERGILLOSIS	COMMENTS
High risk of invasive aspergillosis	AML/MDS (neutropenic)	Posaconazole: Category A-I recommendation	Efficacy of posaconazole prophylaxis was demonstrated in patients at high risk for invasive aspergillosis (HSCT patients with GVHD and neutropenic patients with AML and MDS)
	HSCT recipients with GVHD	Posaconazole: Category A-I recommendation	

Adapted from Walsh et al. *Clin Infect Dis*. 2008. Available at: <http://www.idsociety.org/content.aspx?id=2656>. Click on Aspergillus 2008 under the Fungi category of Infections by Organism.<sup>1</sup>

A category A-I rating indicates there is good evidence to support a recommendation for use and evidence from  $\geq 1$  properly randomized, controlled trial.

Please see reverse side for Indications and Important Safety Information.

## NCCN Clinical Practice Guidelines in Oncology™: Prevention and Treatment of Cancer-Related Infections<sup>2</sup>

OVERALL INFECTION RISK	DISEASE/THERAPY STATE	ANTIFUNGAL PROPHYLAXIS	DURATION
Intermediate to High	AML/MDS (neutropenic)	Posaconazole: Category 1 recommendation	Continue until resolution of neutropenia
	Allogeneic HSCT (neutropenic)	Posaconazole: Category 2B recommendation	Continue during neutropenia and for at least 75 days after transplant
	Significant GVHD*	Posaconazole: Category 1 recommendation	Continue until resolution of significant GVHD

Adapted from NCCN Clinical Practice Guidelines in Oncology: prevention and treatment of cancer-related infections. V.1.2008. Available at: [http://www.nccn.org/professionals/physician\\_gls/PDF/infections.pdf](http://www.nccn.org/professionals/physician_gls/PDF/infections.pdf).<sup>2</sup>

\*Consider antifungal prophylaxis in all patients with GVHD receiving immunosuppressive therapy.

A category 1 rating indicates there is uniform NCCN consensus, based on high-level evidence, that the recommendation is appropriate. A category 2B rating indicates there is nonuniform NCCN consensus (but no major disagreement), based on lower-level evidence including clinical experience, that the recommendation is appropriate.

## Indications

NOXAFIL® is indicated for prophylaxis of invasive *Aspergillus* and *Candida* 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 HSCT recipients with GVHD or those with hematologic malignancies with prolonged neutropenia from chemotherapy.

NOXAFIL® is indicated for the treatment of OPC, including OPC refractory to itraconazole and/or fluconazole.

## 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, pimozide, 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%).

Please see sales representative for full Prescribing Information.

**References:** 1. Walsh TJ, Anaissie EJ, Denning DW, et al. Treatment of aspergillosis: clinical practice guidelines of the Infectious Diseases Society of America. *Clin Infect Dis*. 2008;46:327-360. Available at: <http://www.idsociety.org/content.aspx?id=2656>. Accessed January 18, 2008. 2. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: prevention and treatment of cancer-related infections. V.1.2008. Available at: [http://www.nccn.org/professionals/physician\\_gls/PDF/infections.pdf](http://www.nccn.org/professionals/physician_gls/PDF/infections.pdf). Published January 16, 2008. Accessed January 24, 2008.



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