



Prior Authorization Approval Criteria
Department of Pharmacy Services

Generic Name: posaconazole

Brand Name: Noxafil®

Medication Class: triazole antifungal agent

FDA Approved Uses: 1.) Prophylaxis of invasive *Aspergillus fumigatus* and *Candida* infections in patients ≥ 13 years old who are at risk of developing these infections due to immuno-compromised state caused by the following conditions:

- hematopoietic stem cell transplant (HSCT) recipients with Graft-vs-Host Disease (GVHD) OR
- hematological malignancies with prolonged neutropenia from chemotherapy

2.) Treatment of oropharyngeal *Candidiasis* infections, including cases of oropharyngeal *Candidiasis* infection refractory to fluconazole and/or itraconazole.

Available Dosage Forms: oral suspension

Usual Dose: 1.) Prophylaxis of invasive *Aspergillus* and *Candida* infections: dose is 200 mg (5 mL) oral suspension 3 times a day.
2.) Oropharyngeal *Candidiasis*: Loading dose is 100 mg (2.5 mL) twice a day on the first day, then 100 mg (2.5 mL) once a day for thirteen days.
3.) Oropharyngeal *Candidiasis* refractory to fluconazole and/or itraconazole: 400 mg (10 mL) twice a day. The duration of therapy is based on underlying disease and clinical response.

Duration of Therapy: The duration of therapy is based on severity of underlying disease and on clinical response.

Approximate cost (based on AWP 2006): Depending on the dose a 2 week course of treatment can cost between \$214.00 - \$ 1600.00.

Criteria for Use: *(bullet points below are all inclusive unless otherwise noted)*

- Patient ≥ 13 years old who is recipient of hematopoietic stem cell transplant (HSCT) with Graft-vs-Host Disease (GVHD) and who is at risk of developing invasive *Aspergillus fumigatus* and/or *Candida* infections.

Or

- Patient ≥ 13 years old with hematological malignancies causing prolonged neutropenia from chemotherapy and who is at risk of developing *Aspergillus fumigatus* and/or *Candida* infections

Or



- Clinically documented Oropharyngeal *Candidiasis* infection
 - Fungal culture and other relevant laboratory studies (including histopathology) obtained to isolate and identify causative organisms.

Or

- Clinically documented Oropharyngeal *Candidiasis* refractory to standard course of fluconazole and/or itraconazole.

Criteria for Continuation of Therapy:

- Failure to improve, or worsening of OPC infection after a standard course of therapy with fluconazole and /or itraconazole

Cautions:

- Use caution when patient has demonstrated hypersensitivity to other azoles: no cross-reactivity data is available.
- Use caution in patients with hepatic impairment: data insufficient to recommend dosage reduction.
- Use caution in patients with renal impairment: no dosage reduction is necessary, but range of AUC is more highly varied in renal insufficiency. Monitor closely for breakthrough fungal infections.
- Co-administration of cimetidine, rifabutin and phenytoin should be avoided unless benefit outweighs risk.
- Dose reductions and monitoring is necessary with co-administration of cyclosporine and tacrolimus
- Dose reduction and monitoring is necessary with co-administration of midazolam.
- Administer with caution to patients with potential pro-arrhythmic conditions.
- Drugs metabolized via CYP3A4 may need dose reduction/monitoring for increased ADR (notably, statins and calcium channel blockers).

Monitoring:

- Correction of any electrolyte imbalances should be assured before starting posaconazole (to prevent cardiac events).
- Liver Function Tests (AST, ALT, alkaline phosphatase, Total Bilirubin) should be evaluated before and during the course of therapy. Elevations of LFTs and bilirubin indicate that the patient should be evaluated for hepatic injury. Consider discontinuation of drug if signs/symptoms of hepatic injury develop.
- Monitor diabetic patients who are taking glipizide concurrently with posaconazole for decreases in glucose concentration

Contraindications:

- Hypersensitivity to the active substance or any of its substituents.
- Co-administration with ergot alkaloids (risk of ergotism).
- Co-administration with CYP3A4 substrates increases C_p of these agents; terfenadine, astemizole, cisapride, halofantrine, or quinidine (can lead to QTc prolongation, Torsades de Pointes).



Not Approved if:

- Patient has any contraindications to use of posaconazole.
- Patient does not meet above stated guideline criteria for approval.

P&T Approval: _____ Date: _____