

HIGHLIGHTS OF PRESCRIBING INFORMATION
 These highlights do not include all the information needed to use POSACONAZOLE safely and effectively. Full prescribing information is available at [www.accessdata.fda.gov/drugattribution/2013/01/11/020222Orig1s01.pdf](#).
Indications and Usage (1)
 Dosage and Administration (2)
 Contraindications and Warnings (3)
 Warnings and Precautions (3)
 1/2022

INDICATIONS AND USAGE
 Posaconazole is an azole antifungal indicated as follows:
 • **Posaconazole delayed-release tablets** are indicated for the treatment of invasive aspergillosis in adults and pediatric patients 13 years of age and older. (1.1)
 • **Posaconazole oral suspension** is indicated for the prophylaxis of invasive Aspergillus and Candida infections in patients who are at high risk of developing these infections due to being severely immunocompromised, such as cancer patients who are receiving hematopoietic stem cell transplant, or those with hematologic malignancies with prolonged neutropenia from chemotherapy. (1.2)
 • **Posaconazole delayed-release tablets** are indicated for the prophylaxis of invasive Aspergillus and Candida infections in adults and pediatric patients 2 years of age and older who weigh greater than 40 kg.
 • **Posaconazole oral suspension**, adults and pediatric patients 13 years of age and older.
 • **Posaconazole oral suspension** is indicated for the treatment of oropharyngeal candidiasis, including OTC refractory (OPC) to itraconazole and/or fluconazole in adult and pediatric patients aged 13 years and older. (1.3)

CONTRAINDICATIONS AND WARNINGS AND PRECAUTIONS
 • Concomitant administration of posaconazole with cyclosporin or tacrolimus, reduce doses of cyclosporin and tacrolimus concentrations frequently. (5.1)
 • **Arhythmias and QTc Prolongation:** Posaconazole has been shown to prolong the QTc interval and cause cases of TdP. Administer with caution to patients with potentially proarrhythmic conditions. Do not administer with other antiarrhythmic drugs. (5.2)
 • **Electrolyte Disturbances:** Monitor and correct, especially those involving potassium (K⁺), magnesium (Mg²⁺), and calcium (Ca²⁺) before and during posaconazole treatment. (5.2)
 • **Hepatic Toxicity:** Elevations in liver tests may occur. Discontinuation should be considered in patients who develop abnormal liver tests or monitor liver tests during treatment. (5.4)
 • **Neutropenia:** Concomitant administration of azole antifungals, including posaconazole, with vincristine has been associated with neutropathy and other serious adverse reactions; reserve azole antifungals, including posaconazole, for patients receiving a white blood cell transfusion. (5.4)
 • **Breakthrough Fungal Infections:** Monitor patients for severe diarrhea or vomiting when receiving posaconazole delayed-release tablets with or without food. (2.1)
 • **Neutropenia:** Concomitant administration of posaconazole with vincristine may increase vincristine toxicities, including the risk of tumor lysis syndrome, neutropenia, and serious infections; monitor for and reduce vincristine doses. (4.6, 5.4, 7.1)

ADVERSE REACTIONS
 • Common adverse reactions in studies with posaconazole are diarrhea, nausea, fever, vomiting, headache, and dyspepsia. (7.1)
ADVERSE REACTIONS TO POSACONAZOLE OR NOXAFIL
 • In some cases, adverse reactions may cause fatal harm. (8.1)
 • **Diarrhea:** Based on an analysis, more cases than fatal have been established. (8.4)
 • **Neutropenia:** Based on an analysis, more cases than fatal have been established. (8.4)
 • **Neutropenia:** Based on an analysis, more cases than fatal have been established. (8.4)
 • **Neutropenia:** Based on an analysis, more cases than fatal have been established. (8.4)
 • **Neutropenia:** Based on an analysis, more cases than fatal have been established. (8.4)

DRUG INTERACTIONS
 • **Pharmacokinetic Interactions:** Posaconazole may increase plasma concentrations of cyclosporin and tacrolimus, reduce plasma concentrations of cyclosporin and tacrolimus, and increase plasma concentrations of cyclosporin and tacrolimus. (5.1)
 • **Pharmacodynamic Interactions:** Posaconazole may increase plasma concentrations of cyclosporin and tacrolimus, reduce plasma concentrations of cyclosporin and tacrolimus, and increase plasma concentrations of cyclosporin and tacrolimus. (5.1)

DRUG INTERACTIONS (continued)
 • **Pharmacokinetic Interactions:** Posaconazole may increase plasma concentrations of cyclosporin and tacrolimus, reduce plasma concentrations of cyclosporin and tacrolimus, and increase plasma concentrations of cyclosporin and tacrolimus. (5.1)
 • **Pharmacodynamic Interactions:** Posaconazole may increase plasma concentrations of cyclosporin and tacrolimus, reduce plasma concentrations of cyclosporin and tacrolimus, and increase plasma concentrations of cyclosporin and tacrolimus. (5.1)

USE IN SPECIFIC POPULATIONS
 • **Pediatric:** Posaconazole is indicated for the treatment of invasive aspergillosis in adults and pediatric patients 13 years of age and older. (1.1)
 • **Geriatric:** Posaconazole is indicated for the treatment of invasive aspergillosis in adults and pediatric patients 13 years of age and older. (1.1)
 • **Sexual Activity:** Posaconazole is indicated for the treatment of invasive aspergillosis in adults and pediatric patients 13 years of age and older. (1.1)

HOW SUPPLIED/STORAGE AND HANDLING
 • **Posaconazole delayed-release tablets:** are available as yellow, coated, oblong tablets, debossed with "P" on one side and "200 mg" on the other side.
 • **Posaconazole oral suspension:** is a white, cherry-flavored emulsion with a concentration of 100 mg/5 mL.

HOW SUPPLIED/STORAGE AND HANDLING (continued)
 • **Posaconazole oral suspension:** is a white, cherry-flavored emulsion with a concentration of 100 mg/5 mL.
 • **Posaconazole delayed-release tablets:** are available as yellow, coated, oblong tablets, debossed with "P" on one side and "200 mg" on the other side.

HOW SUPPLIED/STORAGE AND HANDLING (continued)
 • **Posaconazole oral suspension:** is a white, cherry-flavored emulsion with a concentration of 100 mg/5 mL.
 • **Posaconazole delayed-release tablets:** are available as yellow, coated, oblong tablets, debossed with "P" on one side and "200 mg" on the other side.

HOW SUPPLIED/STORAGE AND HANDLING (continued)
 • **Posaconazole oral suspension:** is a white, cherry-flavored emulsion with a concentration of 100 mg/5 mL.
 • **Posaconazole delayed-release tablets:** are available as yellow, coated, oblong tablets, debossed with "P" on one side and "200 mg" on the other side.

HOW SUPPLIED/STORAGE AND HANDLING (continued)
 • **Posaconazole oral suspension:** is a white, cherry-flavored emulsion with a concentration of 100 mg/5 mL.
 • **Posaconazole delayed-release tablets:** are available as yellow, coated, oblong tablets, debossed with "P" on one side and "200 mg" on the other side.

HOW SUPPLIED/STORAGE AND HANDLING (continued)
 • **Posaconazole oral suspension:** is a white, cherry-flavored emulsion with a concentration of 100 mg/5 mL.
 • **Posaconazole delayed-release tablets:** are available as yellow, coated, oblong tablets, debossed with "P" on one side and "200 mg" on the other side.

HOW SUPPLIED/STORAGE AND HANDLING (continued)
 • **Posaconazole oral suspension:** is a white, cherry-flavored emulsion with a concentration of 100 mg/5 mL.
 • **Posaconazole delayed-release tablets:** are available as yellow, coated, oblong tablets, debossed with "P" on one side and "200 mg" on the other side.

HOW SUPPLIED/STORAGE AND HANDLING (continued)
 • **Posaconazole oral suspension:** is a white, cherry-flavored emulsion with a concentration of 100 mg/5 mL.
 • **Posaconazole delayed-release tablets:** are available as yellow, coated, oblong tablets, debossed with "P" on one side and "200 mg" on the other side.

HOW SUPPLIED/STORAGE AND HANDLING (continued)
 • **Posaconazole oral suspension:** is a white, cherry-flavored emulsion with a concentration of 100 mg/5 mL.
 • **Posaconazole delayed-release tablets:** are available as yellow, coated, oblong tablets, debossed with "P" on one side and "200 mg" on the other side.

HOW SUPPLIED/STORAGE AND HANDLING (continued)
 • **Posaconazole oral suspension:** is a white, cherry-flavored emulsion with a concentration of 100 mg/5 mL.
 • **Posaconazole delayed-release tablets:** are available as yellow, coated, oblong tablets, debossed with "P" on one side and "200 mg" on the other side.

HOW SUPPLIED/STORAGE AND HANDLING (continued)
 • **Posaconazole oral suspension:** is a white, cherry-flavored emulsion with a concentration of 100 mg/5 mL.
 • **Posaconazole delayed-release tablets:** are available as yellow, coated, oblong tablets, debossed with "P" on one side and "200 mg" on the other side.

HOW SUPPLIED/STORAGE AND HANDLING (continued)
 • **Posaconazole oral suspension:** is a white, cherry-flavored emulsion with a concentration of 100 mg/5 mL.
 • **Posaconazole delayed-release tablets:** are available as yellow, coated, oblong tablets, debossed with "P" on one side and "200 mg" on the other side.

HOW SUPPLIED/STORAGE AND HANDLING (continued)
 • **Posaconazole oral suspension:** is a white, cherry-flavored emulsion with a concentration of 100 mg/5 mL.
 • **Posaconazole delayed-release tablets:** are available as yellow, coated, oblong tablets, debossed with "P" on one side and "200 mg" on the other side.

HOW SUPPLIED/STORAGE AND HANDLING (continued)
 • **Posaconazole oral suspension:** is a white, cherry-flavored emulsion with a concentration of 100 mg/5 mL.
 • **Posaconazole delayed-release tablets:** are available as yellow, coated, oblong tablets, debossed with "P" on one side and "200 mg" on the other side.

HOW SUPPLIED/STORAGE AND HANDLING (continued)
 • **Posaconazole oral suspension:** is a white, cherry-flavored emulsion with a concentration of 100 mg/5 mL.
 • **Posaconazole delayed-release tablets:** are available as yellow, coated, oblong tablets, debossed with "P" on one side and "200 mg" on the other side.

HOW SUPPLIED/STORAGE AND HANDLING (continued)
 • **Posaconazole oral suspension:** is a white, cherry-flavored emulsion with a concentration of 100 mg/5 mL.
 • **Posaconazole delayed-release tablets:** are available as yellow, coated, oblong tablets, debossed with "P" on one side and "200 mg" on the other side.

HOW SUPPLIED/STORAGE AND HANDLING (continued)
 • **Posaconazole oral suspension:** is a white, cherry-flavored emulsion with a concentration of 100 mg/5 mL.
 • **Posaconazole delayed-release tablets:** are available as yellow, coated, oblong tablets, debossed with "P" on one side and "200 mg" on the other side.

HOW SUPPLIED/STORAGE AND HANDLING (continued)
 • **Posaconazole oral suspension:** is a white, cherry-flavored emulsion with a concentration of 100 mg/5 mL.
 • **Posaconazole delayed-release tablets:** are available as yellow, coated, oblong tablets, debossed with "P" on one side and "200 mg" on the other side.

HOW SUPPLIED/STORAGE AND HANDLING (continued)
 • **Posaconazole oral suspension:** is a white, cherry-flavored emulsion with a concentration of 100 mg/5 mL.
 • **Posaconazole delayed-release tablets:** are available as yellow, coated, oblong tablets, debossed with "P" on one side and "200 mg" on the other side.

HOW SUPPLIED/STORAGE AND HANDLING (continued)
 • **Posaconazole oral suspension:** is a white, cherry-flavored emulsion with a concentration of 100 mg/5 mL.
 • **Posaconazole delayed-release tablets:** are available as yellow, coated, oblong tablets, debossed with "P" on one side and "200 mg" on the other side.

HOW SUPPLIED/STORAGE AND HANDLING (continued)
 • **Posaconazole oral suspension:** is a white, cherry-flavored emulsion with a concentration of 100 mg/5 mL.
 • **Posaconazole delayed-release tablets:** are available as yellow, coated, oblong tablets, debossed with "P" on one side and "200 mg" on the other side.

HOW SUPPLIED/STORAGE AND HANDLING (continued)
 • **Posaconazole oral suspension:** is a white, cherry-flavored emulsion with a concentration of 100 mg/5 mL.
 • **Posaconazole delayed-release tablets:** are available as yellow, coated, oblong tablets, debossed with "P" on one side and "200 mg" on the other side.

HOW SUPPLIED/STORAGE AND HANDLING (continued)
 • **Posaconazole oral suspension:** is a white, cherry-flavored emulsion with a concentration of 100 mg/5 mL.
 • **Posaconazole delayed-release tablets:** are available as yellow, coated, oblong tablets, debossed with "P" on one side and "200 mg" on the other side.

HOW SUPPLIED/STORAGE AND HANDLING (continued)
 • **Posaconazole oral suspension:** is a white, cherry-flavored emulsion with a concentration of 100 mg/5 mL.
 • **Posaconazole delayed-release tablets:** are available as yellow, coated, oblong tablets, debossed with "P" on one side and "200 mg" on the other side.

HOW SUPPLIED/STORAGE AND HANDLING (continued)
 • **Posaconazole oral suspension:** is a white, cherry-flavored emulsion with a concentration of 100 mg/5 mL.
 • **Posaconazole delayed-release tablets:** are available as yellow, coated, oblong tablets, debossed with "P" on one side and "200 mg" on the other side.

HOW SUPPLIED/STORAGE AND HANDLING (continued)
 • **Posaconazole oral suspension:** is a white, cherry-flavored emulsion with a concentration of 100 mg/5 mL.
 • **Posaconazole delayed-release tablets:** are available as yellow, coated, oblong tablets, debossed with "P" on one side and "200 mg" on the other side.

HOW SUPPLIED/STORAGE AND HANDLING (continued)
 • **Posaconazole oral suspension:** is a white, cherry-flavored emulsion with a concentration of 100 mg/5 mL.
 • **Posaconazole delayed-release tablets:** are available as yellow, coated, oblong tablets, debossed with "P" on one side and "200 mg" on the other side.

HOW SUPPLIED/STORAGE AND HANDLING (continued)
 • **Posaconazole oral suspension:** is a white, cherry-flavored emulsion with a concentration of 100 mg/5 mL.
 • **Posaconazole delayed-release tablets:** are available as yellow, coated, oblong tablets, debossed with "P" on one side and "200 mg" on the other side.

HOW SUPPLIED/STORAGE AND HANDLING (continued)
 • **Posaconazole oral suspension:** is a white, cherry-flavored emulsion with a concentration of 100 mg/5 mL.
 • **Posaconazole delayed-release tablets:** are available as yellow, coated, oblong tablets, debossed with "P" on one side and "200 mg" on the other side.

HOW SUPPLIED/STORAGE AND HANDLING (continued)
 • **Posaconazole oral suspension:** is a white, cherry-flavored emulsion with a concentration of 100 mg/5 mL.
 • **Posaconazole delayed-release tablets:** are available as yellow, coated, oblong tablets, debossed with "P" on one side and "200 mg" on the other side.

Pharmacokinetics of Aspergillus and Candida: In a 2 randomized, comparative study, posaconazole (Noxafil Oral Suspension Study 1) and 2L, the safety of posaconazole 200 mg three times a day was compared to itraconazole 400 mg once daily or itraconazole 200 mg twice a day in severely immunocompromised patients.
 The most frequently reported adverse reactions (>30%) in the randomized clinical trials were fever, diarrhea, and nausea. (7.1)
 The most common adverse reactions leading to discontinuation of Noxafil in the prophylaxis studies associated with the disorders, specifically, nausea (2%), vomiting (2%), and hepatic enzymes increased (2%).

Table 1. Noxafil Oral Suspension Study 1 and Study 2 Adverse Reactions in Least 10% of the Noxafil Oral Suspension and Posaconazole Tablets Groups (Positively Proportionally Adjusted)

| Body System | Noxafil Oral Suspension | | Posaconazole Tablets | |
|---|-------------------------|-------|----------------------|-------|
| | n (%) | n (%) | n (%) | n (%) |
| Subjects Reporting any Adverse Reaction | 505 | 138 | 551 | 100 |
| Body as a Whole - General Disorders | | | | |
| Fever | 274 | 160 | 254 | 47 |
| Headache | 117 | 109 | 141 | 32 |
| Rigors | 122 | 100 | 87 | 16 |
| Fatigue | 101 | 117 | 98 | 11 |
| Diarrhea | 59 | 117 | 117 | 25 |
| Malaise | 92 | 115 | 94 | 17 |
| Anorexia | 92 | 115 | 94 | 17 |
| Dizziness | 64 | 111 | 56 | 10 |
| Chills | 58 | 110 | 59 | 10 |
| Weakness | 51 | 108 | 52 | 10 |
| Clinical Laboratory Abnormalities | | | | |
| Cardiovascular/Respiratory Disorders | | | | |
| Hypernatremia | 100 | 110 | 60 | 11 |
| Hypertension | 83 | 114 | 79 | 15 |
| Disorders of Blood and Lymphatic System | | | | |
| Anemia | 149 | 129 | 124 | 23 |
| Leukopenia | 105 | 112 | 102 | 19 |
| Disorders of the Reproductive System and Breast | | | | |
| Vaginal Hemorrhage* | 24 | 110 | 20 | 8 |
| Metabolic and Nutritional Disorders | | | | |
| Diarrhea | 256 | 142 | 212 | 35 |
| Nausea | 222 | 138 | 188 | 37 |
| Hyperkalemia | 187 | 138 | 167 | 31 |
| Abdominal Pain | 161 | 127 | 147 | 27 |
| Constipation | 126 | 121 | 94 | 17 |
| Dyspepsia | 61 | 110 | 50 | 9 |
| Neurologic and Rhythm Disorders | | | | |
| Tachycardia | 72 | 112 | 75 | 14 |
| Infection and Infestations | | | | |
| Fungal Infection | 71 | 112 | 60 | 11 |
| Liver and Biliary System Disorders | | | | |
| Hyperbilirubinemia | 59 | 110 | 51 | 10 |
| Metabolic and Nutritional Disorders | | | | |
| Hypokalemia | 181 | 100 | 142 | 26 |
| Hypomagnesemia | 110 | 118 | 84 | 16 |
| Hypophosphatemia | 88 | 111 | 78 | 14 |
| Hypocalcemia | 56 | 99 | 58 | 10 |
| Musculoskeletal System Disorders | | | | |
| Musculoskeletal Pain | 95 | 118 | 82 | 15 |
| Back Pain | 63 | 110 | 66 | 12 |
| Pain | 63 | 110 | 66 | 12 |
| Psychiatric Disorders | | | | |
| Insomnia | 175 | 108 | 146 | 27 |
| Fatigue | 64 | 111 | 54 | 10 |
| Psychiatric Disorders | | | | |
| Depression | 103 | 117 | 92 | 17 |
| Neurologic System Disorders | | | | |
| Coughing | 146 | 124 | 130 | 24 |
| Dyspnea | 121 | 120 | 116 | 22 |
| Upper Respiratory Tract Infection | 82 | 124 | 73 | 14 |
| Skin and Subcutaneous Tissue Disorders | | | | |
| Rash | 113 | 119 | 96 | 18 |
| Pruritus | 61 | 119 | 61 | 11 |
| Sweating Increased | 153 | 110 | 146 | 27 |
| Sweating Decreased | 64 | 111 | 54 | 10 |
| Other | | | | |
| Neutropenia | 214 | 81 | 213 | 41 |
| Anemia | 112 | 82 | 112 | 21 |
| Disorders of Blood and Lymphatic System | | | | |
| Neutropenia | 214 | 81 | 213 | 41 |
| Anemia | 112 | 82 | 112 | 21 |
| Disorders of the Reproductive System and Breast | | | | |
| Vaginitis | 58 | 100 | 58 | 11 |
| Disorders of Blood and Lymphatic System | | | | |
| Neutropenia | 58 | 100 | 58 | 11 |
| Anemia | 58 | 100 | 58 | 11 |
| Disorders of the Reproductive System and Breast | | | | |
| Vaginitis | 58 | 100 | 58 | 11 |
| Disorders of Blood and Lymphatic System | | | | |
| Neutropenia | 58 | 100 | 58 | 11 |
| Anemia | 58 | 100 | 58 | 11 |
| Disorders of the Reproductive System and Breast | | | | |
| Vaginitis | 58 | 100 | 58 | 11 |
| Disorders of Blood and Lymphatic System | | | | |
| Neutropenia | 58 | 100 | 58 | 11 |
| Anemia | 58 | 100 | 58 | 11 |
| Disorders of the Reproductive System and Breast | | | | |
| Vaginitis | 58 | 100 | 58 | 11 |
| Disorders of Blood and Lymphatic System | | | | |
| Neutropenia | 58 | 100 | 58 | 11 |
| Anemia | 58 | 100 | 58 | 11 |
| Disorders of the Reproductive System and Breast | | | | |
| Vaginitis | 58 | 100 | 58 | 11 |
| Disorders of Blood and Lymphatic System | | | | |
| Neutropenia | 58 | 100 | 58 | 11 |
| Anemia | 58 | 100 | 58 | 11 |
| Disorders of the Reproductive System and Breast | | | | |
| Vaginitis | 58 | 100 | 58 | 11 |
| Disorders of Blood and Lymphatic System | | | | |
| Neutropenia | 58 | 100 | 58 | 11 |
| Anemia | 58 | 100 | 58 | 11 |
| Disorders of the Reproductive System and Breast | | | | |
| Vaginitis | 58 | 100 | 58 | 11 |
| Disorders of Blood and Lymphatic System | | | | |
| Neutropenia | 58 | 100 | 58 | 11 |
| Anemia | 58 | 100 | 58 | 11 |
| Disorders of the Reproductive System and Breast | | | | |
| Vaginitis | 58 | 100 | 58 | 11 |
| Disorders of Blood and Lymphatic System | | | | |
| Neutropenia | 58 | 100 | 58 | 11 |
| Anemia | 58 | 100 | 58 | 11 |
| Disorders of the Reproductive System and Breast | | | | |
| Vaginitis | 58 | 100 | 58 | 11 |
| Disorders of Blood and Lymphatic System | | | | |
| Neutropenia | 58 | 100 | 58 | 11 |
| Anemia | 58 | 100 | 58 | 11 |
| Disorders of the Reproductive System and Breast | | | | |
| Vaginitis | 58 | 100 | 58 | 11 |
| Disorders of Blood and Lymphatic System | | | | |
| Neutropenia | 58 | 100 | 58 | 11 |
| Anemia | 58 | 100 | 58 | 11 |
| Disorders of the Reproductive System and Breast | | | | |
| Vaginitis | 58 | 100 | 58 | 11 |
| Disorders of Blood and Lymphatic System | | | | |
| Neutropenia | 58 | 100 | 58 | 11 |
| Anemia | 58 | 100 | 58 | 11 |
| Disorders of the Reproductive System and Breast | | | | |
| Vaginitis | 58 | 100 | 58 | 11 |
| Disorders of Blood and Lymphatic System | | | | |
| Neutropenia | 58 | 100 | 58 | 11 |
| Anemia | 58 | 100 | 58 | 11 |
| Disorders of the Reproductive System and Breast | | | | |
| Vaginitis | 58 | 100 | 58 | 11 |
| Disorders of Blood and Lymphatic System | | | | |
| Neutropenia | 58 | 100 | 58 | 11 |
| Anemia | 58 | 100 | 58 | 11 |
| Disorders of the Reproductive System and Breast | | | | |
| Vaginit | | | | |

