Prescription Required

Manufacturer: STRIDES PHARMA NDC 64380082706

Ketoconazole 200 Mg Tablet

GENERIC

$1.98 / Tablet

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- 10 +

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Product Information

Uses **Dosage and Administration** **Cautions** **Drug Interactions** **Pharmacokinetics**

Uses

Oral ketoconazole has been used as an alternative for the treatment of blastomycosis, chromomycosis (chromoblastomycosis), coccidioidomycosis, histoplasmosis, and paracoccidioidomycosis.*Because ketoconazole has been associated with serious adverse effects (e.g., hepatotoxicity, adrenal insufficiency) and drug interactions, the drug should be used for the treatment of these systemic fungal infections only when they are serious or life-threatening, other effective antifungals are not available or not tolerated, and the potential benefits of oral ketoconazole outweigh potential risks of the drug.*(See Cautions: Precautions and Contraindications.)

Although oral ketoconazole has been used in the past for the treatment of certain *Candida* infections (e.g., oropharyngeal and/or esophageal candidiasis, vulvovaginal candidiasis, candiduria, chronic mucocutaneous candidiasis) and the treatment of dermatophyte infections (e.g., tinea capitis, tinea corporis, tinea pedis, tinea unguium [onychomycosis]), the drug is no longer recommended and no longer labeled by FDA for these uses.*Because skin and nail fungal infections in otherwise healthy individuals are not life-threatening, risks associated with oral ketoconazole outweigh benefits of the drug in patients with these infections.* Therefore, oral ketoconazole should not be used for the treatment of mucocutaneous or skin infections caused by *Candida* and should not be used for the treatment of dermatophyte infections of the skin or nails. For use of ketoconazole in the topical treatment of dermatophytoses and superficial mycoses,

Oral ketoconazole has been used for the palliative treatment of Cushing's syndrome (hypercortisolism), including adrenocortical hyperfunction associated with adrenal or pituitary adenoma or ectopic corticotropin-secreting tumors. Based on ketoconazole's endocrine effects, the drug has been used in the treatment of advanced prostatic carcinoma. Oral ketoconazole also has been used in the tre t of hypercalcemia in patients with sarcoidosis and the treatment of tuberculosis-associated hypercalcemia and idiopathic infantile hypercalcemia and hypercalciuria.

Blastomycosis

Oral ketoconazole has been used as an alternative for the treatment of blastomycosis caused by *Blasto[illegible]es dermatitidis*. Ketoconazole should be used for the treatment of blastomycosis *only* if the infect[illegible]s serious or life-threatening, other effective antifungals are not available or not tolerated, and the potential benefits of oral ketoconazole outweigh potential risks of the drug.

IV amphotericin B and oral itraconazole usually are the drugs of choice for the treatment of blastomycosis; oral fluconazole is an alternative.

In initial clinical studies, ketoconazole was effective when used in immunocompetent individuals with mild to moderate pulmonary or extrapulmonary blastomycosis (response rate 70-100%); however, the relapse rate with the drug was 10-14%. Because CSF concentrations of ketoconazole are unpredictable and may be negligible following oral administration and because treatment failures or relapses have been reported, the drug should *not* be used to treat fungal infections that involve the CNS, including cerebral blastomycosis.

For additional information on management of blastomycosis, the current clinical practice guidelines from the Infectious Diseases Society of America (IDSA) available at http://www.idsociety.org should be consulted.

Chromomycosis

Oral ketoconazole has been used as an alternative for the treatment of chromomycosis (chromoblastomycosis) caused by *Phialophora* spp. Ketoconazole should be used for the treatment of chromomycosis *only* if the infection is serious or life-threatening, other effective antifungals are not available or not tolerated, and the potential benefits of oral ketoconazole outweigh potential risks of the drug.

A response to ketoconazole has been obtained in some patients with mild to moderate infections, but not in those with more extensive disease. While optimum regimens for the treatment of chromomycosis have not been identified, other antifungals (e.g., flucytosine alone or in conjunction with amphotericin B or itraconazole) are recommended.

Coccidioidomycosis

Oral ketoconazole has been used as an alternative for the treatment of coccidioidomycosis caused by *Coccidioides immitis*. Ketoconazole should be used for the treatment of coccidioidomycosis *only* if the infection is serious or life-threatening, other effective antifungals are not available or not tolerated, and the potential benefits of oral ketoconazole outweigh potential risks of the drug.

IDSA and others state that an oral azole (fluconazole or itraconazole) usually is recommended for initial treatment of symptomatic pulmonary coccidioidomycosis and chronic fibrocavitary or disseminated (extrapulmonary) coccidioidomycosis, including in individuals with human immunodeficiency virus (HIV) infection. IV amphotericin B is recommended as an alternative and is preferred for initial treatment of severely ill patients who have hypoxia or rapidly progressing disease, for immunocompromised individuals, or when azole antifungals have been ineffective or cannot be used (e.g., pregnant women). Because CSF concentrations of ketoconazole are unpredictable and r[illegible]

negligible following oral administration and because treatment failures or relapses have been reported, the drug should *not* be used to treat fungal infections that involve the CNS, including coccidioidal meningitis.

For additional information on management of coccidioidomycosis, the current clinical practice guidelines from IDSA available at http://www.idsociety.org and the current clinical practice guidelines from the US Centers for Disease Control and Prevention (CDC), National Institutes of Health (NIH), and IDSA on the prevention and treatment of opportunistic infections in HIV-infected individuals available at http://www.aidsinfo.nih.gov should be consulted.

Histoplasmosis

Oral ketoconazole has been used as an alternative for the treatment of histoplasmosis caused by *Histoplasma capsulatum*. Ketoconazole should be used for the treatment of histoplasmosis *only* if the infection is serious or life-threatening, other effective antifungals are not available or not tolerated, and the potential benefits of oral ketoconazole outweigh potential risks of the drug.

The drugs of choice for the treatment of histoplasmosis are IV amphotericin B or oral itraconazole. IV amphotericin B is preferred for initial treatment of severe, life-threatening histoplasmosis, especially in immunocompromised patients such as those with HIV infection. Oral itraconazole generally is used for initial treatment of less severe disease (e.g., mild to moderate acute pulmonary histoplasmosis, chronic cavitary pulmonary histoplasmosis) and as follow-up therapy in the treatment of severe infections after a response has been obtained with IV amphotericin B. Other azole antifungals (fluconazole, ketoconazole, posaconazole, voriconazole) are considered second-line alternatives to oral itraconazole.

For additional information on management of histoplasmosis, the current clinical practice guidelines from IDSA available at http://www.idsociety.org and the current clinical practice guidelines from CDC, NIH, and IDSA on the prevention and treatment of opportunistic infections in HIV-infected individuals available at http://www.aidsinfo.nih.gov should be consulted.

Paracoccidioidomycosis

Oral ketoconazole has been used as an alternative for the treatment of paracoccidioidomycosis (South American blastomycosis) caused by *Paracoccidioides brasiliensis*. Ketoconazole should be used for the treatment of paracoccidioidomycosis *only* if the infection is serious or life-threatening, other effective antifungals are not available or not tolerated, and the potential benefits of oral ketoconazole outweigh potential risks of the drug.

IV amphotericin B is the drug of choice for initial treatment of severe paracoccidioidomycosis. Oral itraconazole is the drug of choice for the treatment of less severe or localized paracoccidioidomycosis and for follow-up therapy of more severe infections after initial treatment with IV amphotericin B.

Cushing's Syndrome

Ketoconazole has been used effectively for the palliative treatment of Cushing's syndrome (hypercortisolism), including adrenocortical hyperfunction associated with adrenal or pituitary adenoma or ectopic corticotropin-secreting tumors. Ketoconazole has been used in a limited

of geriatric patients 75 years or older for the treatment of corticotropin-dependent Cushing's syndrome, and some clinicians suggest that the drug may provide an effective alternative in patients who c[illegible]t tolerate surgical treatment.

Safety and efficacy of ketoconazole for the treatment of Cushing's syndrome have not been established and the drug is not labeled by FDA for this use.

Hirsutism and Precocious Puberty

Although safety and efficacy have not been established, ketoconazole has been used with some success in a limited number of patients for the treatment of dysfunctional hirsutism and in a limited number of boys for the treatment of precocious puberty.

Safety and efficacy of ketoconazole for treatment of hirsutism and precocious puberty have not been established and the drug is not labeled by FDA for these uses.

Hypercalcemia

Although safety and efficacy have not been established, ketoconazole has been used with some success for the treatment of hypercalcemia in adults with sarcoidosis. By competitively inhibiting synthesis of 1,25-dihydroxyvitamin D, ketoconazole may reduce elevated serum concentrations of the vitamin that apparently may contribute to sarcoidosis-associated hypercalcemia. Ketoconazole has been shown to produce a dose-dependent decrease in serum 1,25-dihydroxyvitamin D concentrations in healthy individuals and hypercalcemic patients with primary hyperparathyroidism. However, while ketoconazole generally decreases serum concentrations of the vitamin, the drug has reduced serum calcium concentrations in some, but not all, patients with sarcoidosis-associated hypercalcemia. In addition, hypercalcemia and increased serum 1,25-dihydroxyvitamin D concentrations may recur when ketoconazole dosage is decreased or the drug discontinued. Corticosteroids generally are considered first-line treatment of sarcoidosis-associated hypercalcemia; ketoconazole is considered an alternative in patients who fail to respond to or cannot tolerate corticosteroids.

Ketoconazole has been effective in a few adolescents for the treatment of tuberculosis-associated hypercalcemia. Ketoconazole also has been effective in a few infants for the treatment of idiopathic infantile hypercalcemia and hypercalciuria.

Safety and efficacy of ketoconazole for treatment of hypercalcemia have not been established and the drug is not labeled by FDA for this use.

Prostate Cancer

Because of ketoconazole's ability to inhibit testicular and adrenal steroid synthesis, the drug has been used in the treatment of advanced prostatic carcinoma. Ketoconazole has been used as a first-line agent in a few patients, but usually has been used as second-line hormonal therapy in patients with stage IV recurrent prostatic cancer. A limited number of patients with androgen-independent prostatic cancer have received ketoconazole in conjunction with doxorubicin. Ketoconazole has been used effectively as an adjunct in the acute management of disseminated intravascular coagulation (DIC) associated with prostatic carcinoma in a limited number of patients.

Safety and efficacy of ketoconazole for the treatment of advanced prostate cancer have not [illegible] established and the drug is not labeled by FDA for this use.

Protozoal Infections

Acanthamoeba Infections

Oral ketoconazole has been used in conjunction with topical anti-infective agents (e.g., miconazole, neomycin, metronidazole, propamidine isethionate) in the treatment of *Acanthamoeba* keratitis. Optimum therapy for *Acanthamoeba* keratitis remains to be clearly established, but prolonged local and systemic therapy with multiple anti-infective agents and, often, surgical treatment (e.g., penetrating keratoplasty) are usually required.

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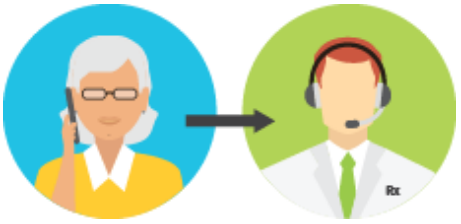

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