

Supplemental Approvals

Generic Name (Trade Name—Company)

December 13, 2018

SUBA-itraconazole

(Tolsura—Mayne Pharma)

FDA approves new formulation of itraconazole for certain systemic fungal infections

Uses/Notes

[Mayne Pharma announced](#) FDA approval of SUBA-itraconazole 65 mg capsules, a new formulation of itraconazole that targets certain systemic fungal infections in adult patients.

The agent is indicated for the treatment of blastomycosis (pulmonary and extrapulmonary), histoplasmosis (including chronic cavitary pulmonary disease and disseminated, nonmeningeal histoplasmosis) and aspergillosis (pulmonary and extrapulmonary, in patients who are intolerant of or who are refractory to amphotericin B therapy).

These serious infections most commonly occur in vulnerable or immunocompromised patients, for example, those with a history of cancer, transplants (solid organ or bone marrow), HIV/AIDS, or chronic rheumatic disorders, and are often associated with high mortality rates or long-term health issues.

The product will launch in January 2019, according to the manufacturer.

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