a nuvista pharma initiative

medevista

Enhanced bioavailability with SUBA Itraconazole
A Comparative Overview

SUBACON®
(Itraconazole 65 mg Capsule)

Suba-Itraconazole to knockout fungal infections

Drug Review

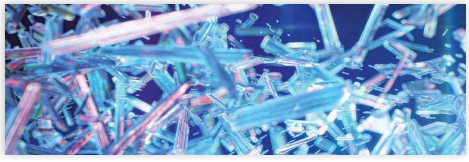
Introduction[1,2,3]

- Fungal infections are increasing worldwide, particularly in warm, humid regions, driving higher rates of dermatophytosis and other mycoses.
- Itraconazole is an antifungal agent used in the treatment of a number of mycoses.[2]
- Conventional itraconazole shows inconsistent bioavailability influenced by food intake, gastric pH, and formulation differences.[2]
- Suba-itraconazole (super-bioavailable itraconazole) delivers improved dissolution and more predictable serum/tissue levels, which may reduce relapse and treatment failure in difficult-to-treat cases.[3]

Comparative Advantages of SUBA Itraconazole Over Conventional Itraconazole[4,5]

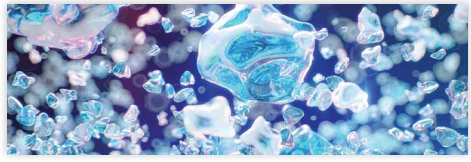
SUBA itraconazole is a novel formulation that overcomes absorption concerns by utilizing a polymer-matrix to disperse active drug and facilitate dissolution. The pH-driven matrix allows concurrent proton pump inhibitor administration without significant effects on drug concentrations. The enhanced bioavailability of SUBA-itraconazole allows for lower dosing, while achieving similar serum concentration as conventional itraconazole.

Conventional Itraconazole
(normal crystaline API)



- Poor bioavailability (only 55%)
- Therapeutic blood level 44%
- Intra or Inter-patient variability
- Requires high daily dose 200 mg (2 x 100 mg)

SUBA Itraconazole
(A solid dispersion of amorphous itraconazole in polymer matrix)



- Super bioavailability up to 90%
- Constant therapeutic blood levels 81%
- Low risk of Intra or Inter-patient variability
- Effective at 35% lower dose 130 mg (2 x 65 mg)

SUBA technology is not a label claim only,
the technology should be proven.

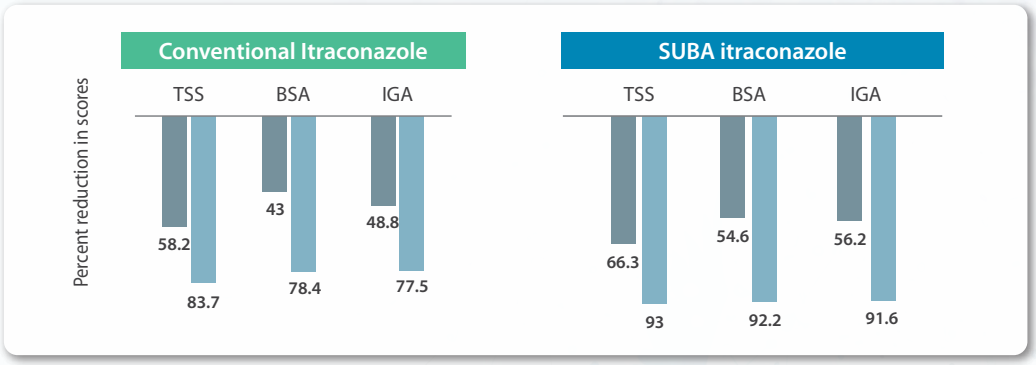
SUBA technology is not merely a formulation improvement but a vital innovation that unlocks the full therapeutic potential of itraconazole. By solving the fundamental issues of poor solubility and erratic absorption, it delivers enhanced efficacy, greater reliability & improved patient care in the management of systemic fungal infections.

Efficacy of SUBA-Itraconazole[6,7]

- Randomized clinical studies report that SUBA-itraconazole was associated with more rapid improvement and higher complete cure rate than conventional itraconazole.

	Complete cure (%)	Mycological cure (%)
C-Itraconzole	33.33	65.38
SUBA-Itraconzole	**66.67**	**84.61**

- Patients treated with SUBA-itraconazole showed greater improvement in the clearance of symptoms as well as lesions in just 2-4 weeks.
- Apart from a complete cure, significant percentage reductions were seen in all mean TSS(Total symptoms score), BSA(Body surface area), and IGA(Investigator's global assessment) scores.



- SUBA-itraconazole was found to be effective in the management of naive, recurrent, and chronic dermatophytosis.
- SUBA-itraconazole has been evaluated in several studies for use as antifungal prophylaxis in immunosuppressed populations(hematopoietic stem cell transplant and lung transplant recipients).
- SUBA-itraconazole was compared with the conventional formulation in a head to head study and fewer adverse events were seen in patients treated with SUBA-itraconazole.

Clinical Implications[8,9]

The enhanced pharmacokinetic profile of SUBA-itraconazole has direct clinical benefits. It is particularly valuable for managing serious invasive fungal infections where reliable and adequate drug exposure is critical. This technology offers several advantages over conventional preparation:

Enhanced Efficacy and Safety Profile

With higher and more consistent drug exposure, SUBA-itraconazole is more likely to achieve and maintain concentrations above the minimum inhibitory concentration (MIC) for pathogens. This translates to improved clinical outcomes. Additionally, the ability to achieve target blood levels with a lower oral dose may reduce the incidence of concentration-related adverse effects.

Reduced Variability and Food Effect

The formulation minimizes the pharmacokinetic variability between patients and reduces the dependency on food or an acidic gastric environment for absorption. This leads to more predictable and consistent plasma concentrations.

Patient Convenience and Adherence

The reduced food effect and lower pill burden (due to higher potency per milligram) support better patient adherence to prescribed regimens, a critical factor in the success of long-term antifungal therapy.

Ref.: 1. Hay RJ, Johns NE, Williams HC, et al. The global burden of skin disease in 2010: an analysis of the prevalence and impact of skin conditions. Lancet. 2014.; 2. Verma S, Madhu R. Recurrent and recalcitrant dermatophytosis: evolving challenges and therapeutic options. Indian J Dermatol Venereol Leprol. 2017.; 3. Lindsay J, et al. Pharmacokinetics and clinical potential of a super-bioavailable itraconazole formulation. Antimicrob Agents Chemother. 2018.; 4. Liu, Jennifer et al. "SUBA-itraconazole in the treatment of systemic fungal infections." Future microbiology vol. 19,13 (2024): 1171-1175. doi:10.1080/17460913.2024.2362128.' 5. FDA approved Tolsura labeling information. 5. Shenoy M, et al. An open-label, randomized, double-arm clinical trial comparing super-bioavailable itraconazole and conventional itraconazole in dermatophytosis. Clin Cosmet Investig Dermatol. 2021.; 6. Ghate S, Dhoot D, Mahajan H, Barkate H. Clinical assessment of super bioavailable Itraconazole 50 mg in dermatophytosis (Clear 50). IP Indian J Clin Exp Dermatol. 2021;7(2):125–129. doi:10.18231/j.ijced.2021.02. 7. Davis MR, et al. The Clinical Pharmacokinetics and Drug-Drug Interactions of Itraconazole and its Formulations. Clin Pharmacokinet. 2023 8. Thompson GR 3rd, et al. SUBA-itraconazole for the treatment of invasive fungal infections. Expert Rev Anti Infect Ther. 2022. 9. Davis MR, et al. The Clinical Pharmacokinetics and Drug-Drug Interactions of Itraconazole and its Formulations. Clin Pharmacokinet. 2023.