

An Open Label Study in Healthy Volunteers to Evaluate the Potential for Cytochrome P450 3A4 Inhibition by F901318 using Oral Midazolam as a Probe.

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Abstract

Background

F901318 a novel orotomide antifungal is

- Intravenous infusions of F901318 at a loading dose of 4 mg/kg bid for 1 day followed by 4 days of maintenance dose at 2.5 mg/kg bid were shown to be safe in healthy volunteers, with an acceptable tolerability profile, as assessed in over 50 subjects.
- Although a small increase in midazolam systemic exposure was seen when midazolam was given concomitantly with F901318, the magnitude of change (1.25 - 2 fold) classes F901318 as a weak CYP3A4 inhibitor.
- As polypharmacy is frequently seen in IA patients, F901318 being a weak CYP3A4 inhibitor is a favourable profile to that seen for the azoles, which are mainly classified as moderate or strong inhibitors of CYP3A4.