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FDA approves Lupin's new generic

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Pharma Major Lupin announced that its US subsidiary, Gavis Pharmaceuticals LLC., (collectively Lupin) has received final approvals for its Voriconazole Tablets, 50 mg & 200 mg and Voriconazole Oral Suspension, 40 mg/mL from the United States Food and Drug Administration (FDA) to market a generic equivalent of PF Prism C.V's Vfend Tablets, 50 mg & 200 mg and Vfend Oral Suspension, 40 mg/mL. Lupin shall commence promoting the products in the US shortly.

Voriconazole Tablets, 50 mg & 200 mg and Voriconazole Oral Suspension, 40 mg/mL are the AB rated generic equivalent of PF Prism C.V's Vfend Tablets, 50 mg & 200 mg and Vfend Oral Suspension, 40 mg/mL. It is indicated for use in patients 12 years of age and older in the treatment of the following fungal infections:
â€¢Invasive Aspergillosis
â€¢Candidemia in Non-neutropenic patients and the following Candida infections: Disseminated infections in skin and infections in abdomen, kidney, bladder wall and wounds
â€¢Esophageal Candidiasis
â€¢Serious fungal infections caused by Scedosporium apiospermum (Asexual form of Pseudallescheria boydii) and Fusarium spp. including Fusarium solani in patients intolerant of or refractory to other therapy

Vfend Tablets, 50mg & 200mg had US sales of $92.8 million (IMS MAT March 2016) while Vfend Oral Suspension, 40 mg/mL had US sales of USD 15.9 million (IMS MAT March 2016).