

Lupin's new generic gets FDA nod

07 June 2016 | News | By BioSpectrum Bureau

Lupin's new generic gets FDA nod



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:

- Invasive Aspergillosis

- Candidemia in Non-neutropenic patients and the following Candida infections: Disseminated infections in skin and infections in abdomen, kidney, bladder wall and wounds

- Esophageal Candidiasis

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