

Mylan launches generic version of Sporanox

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Singapore: Mylan Pharmaceuticals received final approval from the US FDA for its abbreviated new drug application (ANDA) for Itraconazole Capsules, 100 mg. This product is the generic version of Janssen Pharmaceutical's Sporanox.

It is indicated for the treatment of fungal infections that begin in the lungs, blastomycosis, histoplasmosis, and aspergillosis in patients, who are intolerant of or who are refractory to amphotericin B therapy. Itraconazole capsules are also indicated for the treatment of fungal infections of the toenails and fingernails in non-immunocompromised patients.

According to IMS Health, Itraconazole Capsules, 100 mg, reported US sales of approximately \$60 million for the 12 months ending March 31, 2012. Currently, Mylan has 166 ANDAs pending FDA approval representing \$82.6 billion in annual sales. Thirty-five of these pending ANDAs are potential first-to-file opportunities, representing \$25.1 billion in annual brand sales, for the 12 months ending December 31, 2011.

Itraconazole can cause congestive heart failure and should not be given to people with a history of congestive heart failure and should be discontinued if signs or symptoms of congestive heart failure occur. Severe drug interactions, cardiac events and even death could occur if Itraconazole is coadministered with drugs that utilize the same metabolic pathway in the liver, therefore it is important to consult with your doctor before taking Itraconazole and make them aware of all prescribed medications.

Itraconazole has been associated with rare cases of serious hepatotoxicity, including liver failure and death, and should be

discontinued if signs or symptoms of liver disease occur.