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Sun Pharma receives USFDA approval for Methadone HCL

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This is an off-patent drug and is used to treat the pain and opioid addiction. This drug may help generate Sun Pharma big revenues.



Singapore — Sun Pharma has received USFDA approval for Methadone Hydrochloride tablet. Methadone HCL is marketed under the brand Methadose by Specgx LLC. The approval has come for 10mg and 5mg formulations and it is used to treat the pain and opioid addiction.

Methadone HCL market for 5mg and 10mg in 2017 was about ~$75mn. The market is mostly favouring generics and there are already 9-10 generics in this product. Aurobindo Pharma is also selling this generic (~18% market share) while Mallinckrodt is the largest player in this drug with ~50% market share. Mallinckrodt, however has been losing its market share.

Sun Pharma's entry should further reduce the market share of Mallinckrodt.