

Lupin receives FDA approval for Testosterone Gel

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APPROVAL



Pharma major Lupin has announced that it has received approval for its Testosterone Gel, 1.62% (20.25 mg/1.25 g pump actuation), from the United States Food and Drug Administration (FDA) to market a generic version of AbbVie, Inc's (AbbVie) AndroGel 1.62%.

Lupin's Testosterone Gel, 1.62% (20.25 mg/1.25 g pump actuation), is the generic equivalent of AbbVie's AndroGel, 1.62%. It is indicated for replacement therapy in males for conditions associated with a deficiency or absence of endogenous testosterone:

- Primary hypogonadism (congenital or acquired) and
- Hypogonadotropic hypogonadism (congenital or acquired)

Testosterone Gel, 1.62% (20.25 mg/1.25 g pump actuation), (RLD: AndroGel) had annual sales of approximately USD 893 million in the US (IQVIA MAT December 2018).

Lupin is an innovation led transnational pharmaceutical company developing and delivering a wide range of branded & generic formulations, biotechnology products, and APIs globally. The Company is a significant player in the Cardiovascular, Diabetology, Asthma, Pediatric, CNS, GI, Anti-Infective and NSAID space and holds the global leadership position in the Anti-TB segment.

Lupin is the 8th largest generics pharmaceutical company in terms of market capitalization (28th December 2018, Bloomberg) and the 8th largest generics pharmaceutical company in terms of revenues (30th September 2018, Bloomberg LTM) globally. The Company is the 3rd largest pharmaceutical player in the US by prescriptions for the Total Market (IQVIA MAT December 2018); 3rd largest Indian pharmaceutical company by global revenues (30th September 2018, Bloomberg LTM); 6th largest generic pharmaceutical player in Japan (IQVIA MAT December 2018) and 5th largest company in the Indian Pharmaceutical Market (IQVIA MAT December 2018).

For the financial year ended 31st March, 2018, Lupin's Consolidated sales and Net profits before exceptional items were at Rs. 155,598 million (USD 2.41 billion) and Rs. 13,934 million (USD 216 million) respectively.