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Mylan Inc files ANDA for generic Copaxone

NEW DELHI: Drug firm Natco Pharma on Saturday said its marketing partner in America, Mylan Inc has filed an ANDA for generic Copaxone used in treatment of multiple sclerosis and expects 180 days of marketing exclusivity.

The company's marketing partner in the U.S., "Mylan Inc has filed an abbreviated new drug application (ANDA) for a three times a week generic Copaxone and has been accepted by the United States Food and Drug administration (USFDA)," Natco Pharma said in a filing to BSE.

The ANDA is for the product in the strength of 40 mg/ml, it added.

"Mylan believes it is one of the first companies to have filed a substantially complete ANDA containing a Paragraph IV certification for this product and expects to be eligible for 180 days of market exclusivity in the U.S. upon final FDA approval," Natco Pharma said.

According to IMS health, Copaxone 40 mg/ml had U.S. sales of nearly $411.5 million for the 12 months ending June 30, 2014.

In North America, Copaxone is marketed by Teva Neuroscience Inc, a subsidiary of Teva, Natco Pharma said. — PTI

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