

URGENT
PRESS RELEASE



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Wockhardt receives US FDA approval for Alzheimer's drug Memantine

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Pharmaceutical and biotechnology major Wockhardt has received tentative approval from the United States Food & Drug Administration (US FDA) for marketing the 5mg and 10mg tablets of Memantine HCl, which is used for treatment of moderate to severe Alzheimer's disease and dementia. Memantine is the generic name for the brand Namenda, marketed in the United States by Forrest Laboratories. The patent covering this product is under litigation in the US courts. Wockhardt and Forrest Laboratories have reached a settlement on their patent litigation, which will allow Wockhardt to launch its generic version several months ahead of patent expiration or as soon as any other generic version is launched. According to IMS, the total market for Memantine tablets in the US is about \$1.1 billion and is the first in a novel class of Alzheimer's drugs that block NMDA glutamate receptors.

"Wockhardt was amongst the first-to-file for an ANDA with paragraph IV certification on Memantine and is one of the first-to-get a tentative approval," said Wockhardt Chairman Habil Khorakiwala. "This is also one of several other products that Wockhardt has first-to-file ANDA status and such filings are a critical growth factor in the highly competitive US generic market," he further added.

In the US generic pharmaceutical market, Wockhardt has been consistently growing market shares for all its products. In many instances, Wockhardt, by virtue of being amongst the first to market, will gain advantages of being an early entrant.

The Memantine tablets will be manufactured at the US FDA certified formulation plant at Waluj, Aurangabad. The tablets were developed in-house.

Wockhardt is one of the few companies with end-to-end integrated capabilities for its products, starting with manufacture of the oral and sterile API's, the dose forms and marketing through the wholly-owned subsidiary in the US, enabling the company to capture maximum value.

About Wockhardt

Wockhardt is a technology-driven global pharmaceutical and biotechnology major with an innovative multi-disciplinary research and development programme. It has 5 research centres and 14 world-class manufacturing plants dotting various countries and continents that are compliant to international regulatory standards such as the US FDA, MHRA and other global regulatory bodies. It has end-to-end integrated capabilities for its products, starting with manufacture of the oral and sterile API's, the dosage forms and marketing through its wholly owned subsidiary in the US. Wockhardt has a global footprint including the US, UK, Ireland and France with a multi-ethnic workforce from 14 different nationalities.

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