

Dr. Reddy's launches generic Suboxone in the U.S. Market

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Dr. Reddy's launching Buprenorphine and Naloxone Sublingual Film, bilingual film, in the United States market which is used to treat adults with opioid dependence/addiction



Dr. Reddy's Laboratories Ltd. has received final approval from the U.S. Food and Drug Administration (USFDA) and is launching Buprenorphine and Naloxone Sublingual Film, 2 mg/0.5 mg, 4 mg/1 mg, 8 mg/2 mg, and 12 mg/3 mg, a therapeutic equivalent generic version of Suboxone® (buprenorphine and naloxone) sublingual film, in the United States market. The product is being launched with an approved Risk Evaluation and Mitigation Strategy (REMS) Program.

Buprenorphine and naloxone are used to treat adults with opioid dependence/addiction. Buprenorphine helps suppress withdrawal symptoms caused by discontinuation of opioid drugs, and naloxone reverses and blocks the effect of opioids. This combination of medications is used as part of a complete treatment program including prescription monitoring, counseling, and psychosocial support.

In a statement released earlier today by the USFDA, Commissioner Scott Gottlieb, M.D., explained, "The FDA is taking new steps to advance the development of improved treatments for opioid use disorder, and to make sure these medicines are accessible to the patients who need them. That includes promoting the development of better drugs, and also facilitating market entry of generic versions of approved drugs to help ensure broader access."

“With opioid addiction becoming increasingly prevalent in America, the full approval and launch of our generic equivalent of Suboxone® could not have come at a more critical time to help patients,” explains Alok Sonig, Chief Executive Officer, Developed Markets. “We are excited to be launching this important product that will help enable patients to prevail over this insidious disease.”

Sonig adds. “This approval is an important milestone for our company and a testament to our commitment to bring affordable generic medicines to market for patients. Our company will continue to look for opportunities to acquire and manufacture assets that accelerate access to innovative and affordable medicines for patients.”

The Suboxone® brand had U.S. sales of approximately \$1.86 billion MAT for the most recent twelve months ending in April 2018 according to IMS Health.