

First generic cream Estrace launched by Mylan

01 January 2018 | News

Mylan Announces FDA Approval of First Generic for Estrace Cream (MYL)



Global pharmaceutical leader Mylan announced the U.S. launch of Estradiol Vaginal Cream USP, 0.01%, the first generic version of Allergan's Estrace® Cream.

Mylan received final approval from the U.S. Food and Drug Administration (FDA) for its Abbreviated New Drug Application (ANDA) for this product, which is indicated in the treatment of vulvar and vaginal atrophy.

The approval showcases Mylan's ongoing investment in complex products.

Mylan is now one of only a few companies that will offer Estradiol as an option across four delivery systems – cream, gel, transdermal patch and tablet.

Estradiol Vaginal Cream USP, 0.01% had U.S. sales of approximately \$449 million for the 12 months ending Oct. 31, 2017, according to IQVIA.

Currently, Mylan has 211 ANDAs pending FDA approval representing approximately \$93.4 billion in annual brand sales, according to IQVIA.

Forty-six of these pending ANDAs are potential first-to-file opportunities, representing \$42.1 billion in annual brand sales, for the 12 months ending July 31, 2017, according to IQVIA.