

New Drug Manufacturer Report

Section	Data element	Field type	Drug #1	Drug #2	Drug #3
1. Drug Identification	National drug code (11-digit NDC)	Numeric	00527-2800-32	00527-2801-32	00527-2802-32
	Drug name	Text	VARDENAFIL HCL 2.5 mg	VARDENAFIL HCL 5 mg	VARDENAFIL HCL 10 mg
2. Drug Launch Information	Description of the marketing and pricing plans used in the launch of the new drug in the United States and internationally	Text	Lannett sets a single, transparent price per product, regardless of the volume purchased. Lannett sets its VARDENAFIL HCL 2.5 mg prices at approximately cost plus a margin to cover Lannett's overhead and research and development expenses.	Lannett sets a single, transparent price per product, regardless of the volume purchased. Lannett sets its VARDENAFIL HCL 5 mg prices at approximately cost plus a margin to cover Lannett's overhead and research and development expenses.	Lannett sets a single, transparent price per product, regardless of the volume purchased. Lannett sets its VARDENAFIL HCL 10 mg prices at approximately cost plus a margin to cover Lannett's overhead and research and development expenses.
	Estimated volume of patients who may be prescribed the drug	Numeric	14.26	14.26	14.26
	Whether the drug was granted breakthrough therapy designation or priority review by the FDA prior to final approval	Text	Not breakthrough therapy or Priority Review	Not breakthrough therapy or Priority Review	Not breakthrough therapy or Priority Review
	Date and price of acquisition if the drug was not developed by the manufacturer	Text	N/A - product not acquired	N/A - product not acquired	N/A - product not acquired