



## Vytorin<sup>®</sup> (ezetimibe/simvastatin) – First-time generic

- On April 26, 2017, [Impax](#) and [Teva](#) announced the FDA approval and immediate launch of generic versions of Merck's [Vytorin \(ezetimibe/simvastatin\)](#) for the treatment of primary hyperlipidemia and homozygous familial hypercholesterolemia.
  - No incremental benefit of Vytorin on cardiovascular morbidity and mortality over and above that demonstrated for simvastatin has been established.
  - Vytorin has not been studied in Fredrickson type I, III, IV, and V dyslipidemias.
- The [Impax](#) and [Teva](#) products are AB-rated to Vytorin. Teva is the parent company of Watson Laboratories.
- Generic Vytorin will be available as 10 mg/10 mg, 10 mg/20 mg, 10 mg/40 mg and 10 mg/80 mg tablets.
- [Dr. Reddy's](#) also received FDA approval of AB-rated generic versions of Vytorin tablets. The launch date is pending.
- According to IMS Health, the U.S. sales of Vytorin were approximately \$678 million for the 12 months ending in February 2017.



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