

## Welchol® (colesevelam hydrochloride) – First time generic

- On July 17, 2018, <u>Glenmark Pharmaceuticals announced</u> the FDA approval of an <u>AB-rated</u> generic version of Daiichi Sankyo's <u>Welchol<sup>®</sup></u> (<u>colesevelam hydrochloride</u>) packets for oral suspension.
- Welchol is a bile acid sequestrant indicated as an adjunct to diet and exercise to:
  - Reduce elevated low-density lipoprotein cholesterol (LDL-C) in adults with primary hyperlipidemia (Fredrickson Type IIa) as monotherapy or in combination with a hydroxymethyl-glutaryl-coenzyme A (HMG CoA) reductase inhibitor (statin).
  - Reduce LDL-C levels in boys and postmenarchal girls, 10 to 17 years of age, with heterozygous familial hypercholesterolemia as monotherapy or in combination with a statin after failing an adequate trial of diet therapy.
  - Improve glycemic control in adults with type 2 diabetes mellitus.
- Colesevelam hydrochloride is also available generically as an oral tablet and carries the same indications.
- According to IQVIA data, Welchol packets for oral suspension, 1.875 grams/packet and 3.75 grams/packet, achieved annual sales of approximately \$73.0 million ending May 2018.



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