

Immediate Release:

First Generic Version of Cialis® (tadalafil) Commercially Available

New Generic Drug Available: Cialis® (tadalafil)

The first generic version of the blockbuster erectile dysfunction drug, Cialis® (tadalafil), has been approved by the U.S. Food and Drug Administration (FDA) and is now commercially available. Cialis and its generic, tadalafil, are indicated for the treatment of erectile dysfunction (ED), the symptoms/signs of benign prostatic hyperplasia (BPH), and in patients who have both ED and BPH. Cialis and the generic are supplied as oral tablets in the strengths of 2.5 mg, 5 mg, 10 mg, and 20 mg.

Tadalafil works by inhibiting the phosphodiesterase-5 enzyme. Other medications in this drug class include: Stendra® (avanafil), Viagra® (sildenafil), Levitra® (vardenafil), and Staxyn® (vardenafil). The dosing regimen of tadalafil depends on the indication for use. For ED, it can be taken once daily or as needed. For BPH, it is taken as 5 mg once daily. The tablets should not be split and can be taken with or without food.

Use	Dosing Regimen	AWP* per Day for Cialis	AWP* per Day for Generic
ED	Once daily: 2.5 mg to 5 mg	\$13.68	\$13.00
	As needed: 10 mg usually, range 5 mg to 20 mg	\$80.16	\$76.15
BPH	5 mg once daily**	\$13.68	\$13.00

**AWP: average wholesale price **Also the dose used for patients who have ED and BPH.*

Tadalafil should not be used in patients taking any form of nitrates, including isosorbide dinitrate (Isordil®), isosorbide mononitrate, or nitroglycerin, as using these agents together can result in too low of blood pressure. Patients with an allergic reaction to tadalafil or patients taking the pulmonary arterial hypertension medication Adempas® (riociguat) should not use tadalafil. Common side effects include headache, indigestion, back pain, muscle pain, nasal congestion, flushing, and pain in legs or arms.

The generic version is manufactured by Teva and is currently priced at a 5% discount to brand-name Cialis. Teva has been granted six months of exclusivity before the FDA approves additional generic versions of the product which are expected to further reduce the cost. We are planning to review the new generic tadalafil for placement on CastiaRx formularies. For additional information, please view the manufacturer's [press release](#).

References:

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2. Weintraub A. Teva launches first U.S. generic Cialis as Eli Lilly braces for loss of its ED blockbuster.
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4. Lexicomp [online database]. Hudson, OH: Lexi-Comp, Inc. Available at: <http://www.lexicomp.com> [subscription required]. Updated September 26, 2018. Accessed September 27, 2018.

