




FDA Approved Emergency Contraceptive Products Currently on the US Market

	Plan B®	Next Choice™	Plan B® One-Step
			
Formulation	2 tablets (each 0.75mg levonorgestrel)	2 tablets (each 0.75mg levonorgestrel)	1 tablet (1.5mg levonorgestrel)
Manufacturer	Teva Pharmaceuticals, Inc. (formerly Barr Laboratories, LLC)	Watson Pharmaceuticals, Inc.	Teva Pharmaceuticals, Inc.
Approval Date	Prescription: July 28, 1999 OTC: August 24, 2006	Prescription: June 24, 2009 OTC: August 28, 2009	July 10, 2009
Product Availability in Pharmacies	Available in some pharmacies and health centers until supplies run out.	Prescription-only labeled product currently in pharmacies. Dual labeled product to be distributed in Fall 2009 according to Watson.	Currently available in pharmacies.
Type of Labeling/ Over-the-Counter (OTC) & Prescription Access Restrictions	Single product that is “dual labeled” for both prescription and OTC usage with the following restrictions: Rx: 16 years and younger OTC: 17 years and older Product packaging has not and will not be updated with the new FDA approved labeling. Comprehensive labeling information can be found at planbonestep.com .	Single product that is “dual labeled” for both prescription and OTC usage with the following restrictions: Rx: 16 years and younger OTC: 17 years and older Comprehensive labeling information can be found at mynextchoice.com .	Single product that is “dual labeled” for both prescription and OTC usage with the following restrictions: Rx: 16 years and younger OTC: 17 years and older Comprehensive labeling information can be found at planbonestep.com .
Directions on Package Insert	“One tablet of Plan B should be taken orally as soon as possible within 72 hours after unprotected intercourse. The second tablet should be taken 12 hours after the first dose.”	“The first tablet is taken orally as soon as possible within 72 hours after unprotected intercourse. The second tablet should be taken 12 hours after the first dose.”	“One tablet taken orally as soon as possible within 72 hours after unprotected intercourse.”
Approximate Cost	\$35-\$60 ¹	This generic Plan B is currently priced around 10% lower than the branded Plan B. (Actual pharmacy example: Plan B= \$45, Next Choice= \$41)	Plan B One-Step is in the same price range as Plan B, \$35-\$60.
Market Exclusivity* Period	The market exclusivity period for both prescription and OTC Plan B has expired.	There has been no public announcement made about an exclusivity period.	Market exclusivity for Plan B One-Step expires July 10, 2012.
Product Website	N/A: (Plan B’s previous website, www.go2planb.com , now directs you to Plan B One-Step’s website.)	www.mynextchoice.com	www.planbonestep.com

*Market exclusivity is a competition-free period for a drug granted by the FDA, often after a drug approval or the submission of new clinical studies. A generic version of the drug cannot be marketed during this term specified by the FDA.

¹ <http://ec.princeton.edu/questions/eccost.html>

Please contact Lydia Stuckey, lstuckey@rhtp.org, with any questions.

Current as of September 21, 2009

Source: Reproductive Health Technologies Project, Washington, DC.