



FDA Approved Emergency Contraceptive Products Currently on the US Market

	ella® [Product Picture Coming Soon]	Next Choice® 	Plan B® One-Step 
Formulation	1 tablet (30mg ulipristal acetate)	2 tablets (each 0.75mg levonorgestrel)	1 tablet (1.5mg levonorgestrel)
Manufacturer	Watson Pharmaceuticals, Inc.	Watson Pharmaceuticals, Inc.	Teva Pharmaceuticals, Inc.
Approval Date	August 13, 2010	Prescription: June 24, 2009 OTC: August 28, 2009	July 10, 2009
Product Availability in Pharmacies and Health Centers	Ella will be available initially at health clinics beginning in the fourth quarter of 2010, with the goal of nationwide pharmacy access in January 2011.	Currently available in pharmacies and health centers.	Currently available in pharmacies and health centers.
Type of Labeling/ Over-the-Counter (OTC) & Prescription Access Restrictions	Single product labeled for prescription usage. Comprehensive labeling information can be found at http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm222428.htm	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 taken orally as soon as possible, within 120 hours (5 days) after unprotected intercourse or a known or suspected contraceptive failure.”	“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	Not yet known, but as a prescription-only product, ella may be covered by private and public health insurance when it becomes available on the market.	This generic EC is currently priced around 10-20% lower than Plan B One-Step. (Actual pharmacy example from Washington, DC: Plan B One-Step= \$50, Next Choice= \$40.)	\$35-\$60 ¹
Market Exclusivity* Period	Market exclusivity for ella expires August 13, 2015.	Next Choice does not have market exclusivity. Another generic product could enter the market at any time.	Market exclusivity for Plan B One-Step expires July 10, 2012.
Product Website	Not launched yet.	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>