

FDA NEWS RELEASE
For Immediate Release: June 24, 2009

FDA Approves Generic Prescription-Only Version of Plan B Emergency Contraceptive for Women Ages 17 and Under

The U.S. Food and Drug Administration today approved the first generic version of the emergency contraceptive Plan B (levonorgestrel) tablets, 0.75 mg. The generic product will be available by prescription only for women ages 17 and under.

Plan B was first approved in 1999 for prescription use only for women of all ages. Plan B is manufactured by Duramed Pharmaceuticals Inc., of Cincinnati.

In 2006, Plan B was approved for nonprescription use for women ages 18 and older. Plan B remained available as a prescription-only product for women ages 17 and under. Today's approval allows marketing of a prescription-only generic product for women ages 17 and under. No generic levonorgestrel product for emergency contraception can be approved for nonprescription use in women ages 18 and older until Aug. 24, 2009, when the marketing exclusivity held by Duramed for the nonprescription use expires.

The generic levonorgestrel tablets 0.75 mg are made by Watson Laboratories Inc., based in Corona, Calif.

Levonorgestrel can prevent pregnancy after unprotected intercourse or a known or suspected contraceptive failure. It is not effective in terminating an existing pregnancy and does not protect against sexually transmitted diseases, including HIV infection.

For more information: [Generic Drugs](#)

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