



November 15, 2006

Levonorgestrel (Plan B[®])

Available OTC

THE ISSUE

On Nov. 1, 2006, Duramed Pharmaceuticals (a division of Barr Pharmaceuticals) released the over the counter (OTC) package for its brand of emergency contraception – Plan B[®] (levonorgestrel 0.75 mg). This is a direct result of an FDA decision from Aug. 24, 2006, which allowed Duramed to make Plan B[®] available without a prescription.

THE DRUG

Levonorgestrel (Plan B[®]) emergency contraceptive is a high-dose progestin-only contraceptive indicated for prevention of pregnancy in women who have had a primary contraceptive failure with unprotected intercourse. It consists of two doses of levonorgestrel 0.75 mg given twelve hours apart. The primary mechanism of action is delay of ovulation; thus, the medication is most effective if taken as soon as possible or within 72 hours of unprotected intercourse.

OTC STATUS

Upon direction of the FDA, Duramed was tasked with marketing Plan B[®] as an OTC item to be available only to patients age 18 or older. They also directed that it should be stored behind the pharmacy counter and only sold at locations under the control of a pharmacist. The FDA also wanted to make sure that the product would continue to be available to all patients as a prescription product. Duramed thus developed a new, dual package that contains all of the necessary patient information and warnings to sell the product without a prescription. The package is also labeled with a warning indicating that it is “Rx only for age 17 and younger.”

RESOURCE

FDA Plan B[®] Information Page: <http://www.fda.gov/cder/drug/infopage/planB/default.htm>

DISCLAIMER

This publication is intended to provide key practical information regarding this drug product in a brief format. It does not contain sufficient information upon which to base formulary or other medication use policy decisions.

WHAT THE PHARMACIST SHOULD KNOW

Plan B[®] must be stored behind the counter. The previously manufactured package (NDC 51285-0038-93) may continue to be dispensed by prescription only. The new packaging (NDC 51285-0769-93) may be dispensed OTC or Rx. OTC sale is restricted to patients age 18 or older. OTC sale is **not** restricted to women only. Patient must present a valid government-issued ID for age verification. Valid IDs would be similar to those required for pseudoephedrine sales. The DEA has published this listing of acceptable IDs: http://www.deadiversion.usdoj.gov/meth/alternate_ID2.pdf. Signature logs are not required. Pharmacists are not required to dispense product, but must ensure that age verification is being completed. Pharmacists must be available to answer patient questions and concerns. Patients age 17 and younger must have a valid prescription. Plan B[®] is not abortifacient. It will not terminate pregnancy in women who are already pregnant.

WHAT THE PATIENT SHOULD KNOW

- The earlier you take emergency contraception, the more effective it is.
- May cause spotting or breakthrough bleeding.
- May cause regular cycle to occur earlier or later than normal.
- If you are using a primary method of contraception, continue to use it normally.
- If your regular cycle does not occur within 3 days of the regular time, consult a physician for a pregnancy test.
- May cause nausea. May take with food.
- Emergency contraception does not protect against sexually-transmitted infections or diseases.

