



Dear NDA/ANDA Applicant:

This letter is intended to document and communicate FDA's determinations regarding the scope of Teva's exclusivity for Plan B One-Step (PBOS) as a fully over-the-counter (OTC or nonprescription) drug product and appropriate labeling carve outs for ANDAs seeking to reference that drug product. On July 23, 2013, FDA solicited comments from Teva and already approved ANDA holders for PBOS seeking input on the scope of FDA's grant of exclusivity for Teva's product and on ANDA labeling that does not impinge on that protection. In making its determination, FDA has considered letters from Teva dated August 5, 2013, and October 7, 2013, and from Watson dated August 23, 2013, and from Novel dated August 30, 2013, and December 17, 2013.

Factual Background

On January 24, 2006, Teva submitted a new drug application (NDA) to market PBOS, a one-tablet emergency contraceptive product with the same active ingredient (levonorgestrel) and indication as a previously approved product, Plan B, but that differed from Plan B in amount of active ingredient per tablet and dosing regimen. Plan B, a levonorgestrel product with a two-tablet dosing regimen, originally was approved as an emergency contraceptive in July 1999 for prescription use only. In August 2006, Plan B was approved as a nonprescription product for women ages 18 and older, and remained a prescription product for women ages 17 and below. In July 2009, it was approved as a nonprescription product for women ages 17 and older, and remained a prescription product for women ages 16 and below. Although Teva had initially sought permission to market PBOS as a prescription-only product for women of all ages, after Plan B was approved in its dual packaging configuration, Teva subsequently amended its PBOS submission to seek nonprescription approval of PBOS for women ages 17 and older and approval for prescription-only use by women ages 16 and below. On July 10, 2009, FDA approved Teva's application to market PBOS in a single packaging configuration as a nonprescription product for women ages 17 and older, and as a prescription-only product for women ages 16 and below. FDA had previously advised Teva that the actual use studies that it had conducted for Plan B did not support approval as a nonprescription product for women of all ages. To support such approval, Teva was advised that it would have to do an actual use study in the younger age groups to show that the product could be safely used in younger age groups without physician intervention.¹ Teva chose to conduct that study using its PBOS product instead of Plan B.

At the time of the initial PBOS approval in 2009, Teva received 3 years of Hatch-Waxman exclusivity (coded in the Orange Book as New Product exclusivity) for the approval of a one-tablet product in a configuration that, as noted above, was nonprescription for women 17 and

¹ Not-approvable letter to Barr Research, Inc. signed by Dr. Steven Galson, dated May 6, 2004, for NDA 21-045/Supp-011.

older and prescription-only for women 16 and below. Because the approved PBOS product, like the approved Plan B product, was packaged in a dual-packaging configuration so that it was both prescription and nonprescription (depending on the age of the women who sought to use it), the product was held behind the pharmacy counter (and was not sold in retail outlets without pharmacies, such as gas stations and convenience stores) to comply with the federal dispensing requirements at 21 U.S.C. 353(b) (section 503(b) of the Federal Food, Drug, and Cosmetic Act (FD&C Act or Act)). After the approval of PBOS, FDA continued to meet with Teva and provide advice on the type and amount of data that would be necessary to support approval of PBOS as a nonprescription-only product without restriction based on age.²

On February 7, 2011, Teva submitted a supplemental NDA (sNDA) for PBOS seeking to remove the prescription-only status for women ages 16 and below and, instead, seeking approval of the product for nonprescription use for women of all ages. The sNDA included the results of Teva's label comprehension study designed to assess whether women ages 16 and below could comprehend certain key elements concerning the product itself and how it is intended to be used. The sNDA also included the results of an open-label single-arm actual use study in women ages 16 and below to determine the percentage of subjects who correctly self-select and use PBOS under simulated nonprescription conditions.

In her November 30, 2011 summary review of the February 7, 2011 supplement, Dr. Andrea Leonard-Segal, Division Director, Division of Nonprescription Clinical Evaluation ("Division"), evaluated the actual use study for PBOS and stated: "I agree with the medical review team (Drs. Chang, Furlong, Mathis) that the data reviewed for this application have demonstrated that [PBOS] is a safe and effective emergency contraceptive for use by adolescents less than 17 years old without the intervention of a healthcare provider." She further noted that "[t]he actual use study data demonstrate that adolescents can appropriately self-select to use [PBOS] based on their own medical circumstances and that they take the medication properly without healthcare provider intervention." Additionally, she stated "By virtue of the data submitted by Teva in NDA 21-998 S002, [PBOS] meets the requirements...for an OTC drug (21 CFR 310.200) for adolescent females." (See Summary Review for Regulatory Action, November 30, 2011).

Despite Dr. Leonard-Segal's conclusions in her November 30, 2011 summary review, on December 7, 2011, FDA issued a complete response letter to Teva informing Teva that its application was not approved. On that date, two statements were issued regarding that decision. In one statement, FDA Commissioner Margaret Hamburg stated, "I agree with [FDA's Center for Drug Evaluation and Research] that there is adequate and reasonable, well-supported and science-based evidence that [PBOS] is safe and effective and should be approved for nonprescription use for all females of child-bearing potential." See Statement from FDA Commissioner Margaret Hamburg, M.D. on Plan B One-Step (available at <http://www.fda.gov/NewsEvents/Newsroom/ucm282805.htm>) (Hamburg Statement). In a separate statement, Secretary of the Department of Health and Human Services Kathleen G. Sebelius asserted her authority to execute, through FDA, the FD&C Act, and announced that she

² FDA met with Teva on April 28, 2010, and provided advice on necessary data in the actual use study. FDA also met with Teva on June 1, 2009, and provided general advice on the pathway for full OTC status for Plan B and Plan B One-Step.

was directing FDA to issue a complete response (rather than an approval) letter to Teva based on her conclusion that “the data submitted by Teva do not conclusively establish that [PBOS] should be made available over the counter for all girls of reproductive age.” See Statement by U.S. Department of Health and Human Services Secretary Kathleen Sebelius (available at <http://www.hhs.gov/news/press/2011pres/12/20111207a.html>) (Sebelius Statement). Thus, it was determined that Teva still had not submitted sufficient data and information to support approval of PBOS for use without a prescription for women of all ages.

Teva filed a complete response to the December 7, 2011 action letter on March 9, 2012, which was followed by numerous additional submissions. Through those submissions, and relying on the actual use and label comprehension studies submitted in the February 7, 2011 sNDA, Teva sought approval of a nonprescription-only product that would be for sale to women ages 15 and older. The labeling Teva proposed did not include a prescription indication (or any indication) for women 14 and below. On April 30, 2013, FDA approved the sNDA as amended (S-002) to make PBOS available “over the counter to women of childbearing potential aged 15 years and older who are in need of emergency contraception.” Because that sNDA resulted in a nonprescription-only product, upon its approval there was no longer a prescription component to PBOS labeling and, therefore, there was no longer the need to hold PBOS behind the pharmacy counter to ensure that the prescription dispensing requirements under 503(b) of the Act were met. In addition, the approved labeling for the nonprescription PBOS product contained the following statements: “Not for sale to those under 15 years of age; Proof of age required; and Not for sale where age cannot be verified.”

While the drug approval process was ongoing and the Division was communicating with Teva regarding what would be necessary to obtain approval for a nonprescription-only product, FDA was also considering how to respond to a Citizen Petition submitted by the Center for Reproductive Law and Policy (now the Center for Reproductive Rights) on February 14, 2001 (Docket 01P-0075/CP1) on behalf of more than 60 family planning and health organizations. The petition asked FDA to approve certain marketed emergency contraceptives, including Plan B, for use without a prescription by women of all ages without age or point-of-sale restrictions. In January 2005, a group of individuals and reproductive health groups, including one of the petitioners, represented by Center for Reproductive Rights, sued FDA in federal district court for the Eastern District of New York seeking an order requiring FDA to approve Plan B for nonprescription use without age or point of sale restrictions. FDA denied the Citizen Petition on June 9, 2006, on the ground that it was not adequately supported by scientific evidence. The district court vacated that denial and remanded to FDA on March 23, 2009. See *Tummino v. Torti*, 603 F. Supp. 2d 519 (E.D.N.Y. 2009).

On remand, on December 12, 2011, FDA again denied the Citizen Petition based on the lack of adequate data to support nonprescription use of Plan B for women of all ages. On April 5, 2013, the court ruled that “the decisions of the Secretary with respect to Plan B One-Step and that of FDA with respect to the Citizen Petition, which it had no choice but to deny, were arbitrary, capricious, and unreasonable.” See *Tummino v. Hamburg*, No. 12-CV-763 (ERK)(VVP) (E.D.N.Y.) (Memorandum & Order, April 5, 2013 at 56). The court ordered the Commissioner of Food and Drugs and the Secretary of Health and Human Services to grant the Citizen Petition

and make levonorgestrel-based emergency contraceptive drug products (including Plan B and PBOS) available without a prescription to women of all ages without age or point of sale restrictions within 30 days. See *Id.*

On June 10, 2013, the United States Attorney informed the district court of the Government's intention to comply with the court's April 5, 2013 order. On June 12, 2013, the district court issued a Memorandum noting that the Commissioner of Food and Drugs and the Secretary of Health and Human Services have committed to approve "without delay" an sNDA that it expected Teva to submit seeking approval of PBOS for nonprescription use for women of all ages without age or point of sale restriction. See *Tummino v. Hamburg*, No. 12-CV-763 (ERK)(VVP) (E.D.N.Y.) (Memorandum, June 12, 2013 at 4). On June 17, 2013, in response to a supplement request letter FDA sent to comply with the court's order, Teva submitted its sNDA (S-003), which sought approval for nonprescription use of PBOS without age or point of sale restrictions. Consistent with its June 10, 2013 representation to the court, FDA approved S-003 on June 20, 2013, in compliance with the court's orders and based on the label comprehension and actual use studies that Teva had submitted on February 7, 2011.

Statutory and Regulatory Framework

Under the applicable provisions of the FD&C Act, "If a supplement to an application . . . contains reports of new clinical investigations (other than bioavailability studies) essential to approval of the supplement and conducted or sponsored by the person submitting the supplement, the Secretary may not make the approval of an application submitted under this subsection for a change approved in the supplement effective before the expiration of three years from the date of approval of the supplement." 21 U.S.C. 355(j)(5)(F)(iv); See also 21 U.S.C. 355(c)(3)(E)(iv) (505(j)(5)(F)(iv) and 505(c)(3)(E)(iv) of the Act).

Under applicable regulations, a "clinical investigation" means "any experiment other than a bioavailability study in which a drug is administered or dispensed to, or used on, human subjects." 21 C.F.R. 314.108(a).

A "new clinical investigation" is an "investigation in humans the results of which have not been relied on by FDA to demonstrate substantial evidence of effectiveness of a previously approved drug product for any indication or of safety for a new patient population and do not duplicate the results of another investigation that was relied on by the agency to demonstrate the effectiveness or safety in a new patient population of a previously approved drug product." *Id.*

An investigation is conducted or sponsored by the person submitting the supplement if "before or during the investigation, the applicant was named in Form FDA-1571 filed with FDA as the sponsor of the investigational new drug application under which the investigation was conducted, or the applicant or the applicant's predecessor in interest, provided substantial support for the investigation." *Id.*

A new clinical investigation is considered "essential to approval" if, with regard to that investigation, "there are no other data available that could support approval of the application." *Id.* FDA has further explained that an investigation is not considered essential to approval if

there is other information that would be sufficient to provide approval of the change (such as what is already known about a previously approved product or from published literature or other public information that would have supported the change approved in the application). See Preambles to 1989 Proposed Rule and 1994 Final Rule, Abbreviated New Drug Applications; Patent and Exclusivity Provisions, 54 FR 28872 at 28900 and 59 FR 50338 at 50357, respectively.

If an application or supplement earns 3-year exclusivity because it is approved based on new clinical studies that are essential to approval conducted by or for the applicant and the same applicant subsequently obtains approval of an additional application or supplement that references those same clinical studies, technically the studies are no longer “new” for purposes of the second supplement and the change approved in the subsequent application or supplement is not eligible for its own exclusivity period. Under FDA’s longstanding practice, however, if the studies are essential to the approval of the subsequent application or supplement, the subsequent application or supplement would be eligible for the balance of the previously awarded exclusivity period such that its 3-year exclusivity will end on the same date as that of the application or supplement that obtained the original exclusivity period.³ This practice (known informally as the “balance exclusivity” policy) encourages innovation by protecting the 3-year exclusivity previously awarded and expanding its scope when the studies are essential to additional labeling changes that were not approved when the supplement was approved initially, without providing additional exclusivity time for studies that are no longer “new.”

An ANDA (other than a petitioned ANDA under 505(j)(2)(C)) is required to have the “same labeling” as the listed drug it references except for differences due to patent or exclusivity or certain other differences due to difference in manufacturer. 21 C.F.R. 314.94(a)(8)(iv). Permissible differences include “omission of an indication or other aspect of labeling protected by patent or accorded exclusivity under section 505(j)(5)(F) of the act.” *Id.* If certain information in NDA labeling is protected by exclusivity, an ANDA may obtain approval and satisfy the same labeling requirement by carving out the protected information. Such a labeling carve out is permissible, however, only if the drug with the carved out labeling remains safe and effective for the remaining non-protected conditions of use. 21 C.F.R. 314.127(a)(7).

Courts have held that in considering whether to permit a labeling carve out, FDA must consider whether the drug approved under the ANDA with the labeling carved out would be “safe and effective for each indication that will appear on its label; whether the label for the [drug

³ See, e.g. NDA 21872 for Levetiracetam Injection for Adjunctive Therapy in Treatment of Primary Generalized Tonic-Clonic Seizures in Adults and Children 16 Years and Older with Idiopathic Generalized Epilepsy (receiving balance of 3-year exclusivity previously awarded to NDA 21505 for Levetiracetam Oral Solution for Adjunctive Therapy in Treatment of Primary Generalized Tonic-Clonic Seizures in Adults and Children 6 Years and Older with Idiopathic Generalized Epilepsy because it was based on same studies albeit for a different dosage form and narrower subpopulation); NDA 22488 for Pregabalin Oral Solution for Management of Neuropathic Pain Associated with Spinal Cord Injuries (receiving balance of 3-year exclusivity given to NDA 21446 for Pregabalin Capsules for same indication because it was based on same studies albeit for a different dosage form); NDA 203985 for Everolimus Tablets for Suspension for Treatment of Patients with Subependymal Giant Cell Astrocytoma with Tuberous Sclerosis (TS) Who Require Therapeutic Intervention but are not Candidates for Surgical Resection (receiving balance of exclusivity given to NDA 22334 Everolimus Tablets for same indication because it was based on same studies albeit for a different dosage form).

approved under the ANDA] lists every indication approved for use of the pioneer is a matter of indifference.” *Bristol-Myers Squibb v. Shalala*, 91 F.3d 1493,1500 (D.C. Cir. 1996); see also *Sigma-Tau Pharms, Inc. v. Schwetz*, 288 F.3d 141, 146 (4th Cir. 2002)(rejecting a “foreseeable off label use” argument and upholding a labeling carve out in the orphan drug context because the drug, with the protected labeling carved out, remained safe and effective for the remaining non-protected conditions of use).

Teva’s Exclusivity

As noted above, FDA granted 3-year Hatch-Waxman exclusivity for nonprescription use of PBOS by women ages 15 and 16 on April 30, 2013, based on the actual use study Teva conducted. With the June 20, 2013 approval of S-003, under the “balance exclusivity” policy, FDA extended the balance of that exclusivity to nonprescription use of PBOS by women ages 14 and below based on the same study.

We have determined that the actual use study was a new clinical investigation, essential to the approval of S-002 and S-003 approved on April 30, 2013, and June 20, 2013, respectively, and conducted by or for Teva. The study therefore qualifies for 3-year exclusivity under applicable law. The remaining issue is the scope of that exclusivity. Specifically, what was the “change approved in the supplement” for which the study was “essential”?

Teva appears to contend that the actual use study was essential to removal of all point of sale restrictions and approval of PBOS for all nonprescription use.⁴ Teva contends that, at a minimum, generics of PBOS that are sold over the counter must be subject to point of sale restrictions that prevent them from being dispensed to women ages 16 and under for whom they will not be approved during the pendency of the exclusivity. Teva October 5, 2013 Letter at 1. Teva further requests that ANDA labeling include statements that read, “NOT FOR SALE TO THOSE UNDER 17 YEARS OF AGE/ PROOF OF AGE REQUIRED/ NOT FOR SALE WHERE AGE CANNOT BE VERIFIED.” *Id.* at 2-3.

In FDA’s view, however, this characterization of the exclusivity is too broad and Teva’s proposal for conditions on ANDA labeling and marketing is too restrictive. In the absence of the actual use study in women ages 16 and below, and prior to the approval of S-002 and S-003, PBOS was already approved for use without a prescription in women ages 17 and older. It has been approved for nonprescription use in this age group since 2009. As of the April 30, 2013 approval of S-002, Teva’s actual use study was determined to be essential to approval of PBOS for nonprescription use in 15 and 16 year olds. The change approved in S-003 on June 20, 2013, for which the actual use study was essential was the approval of PBOS for use without a prescription in women ages 14 and below. It is nonprescription use in these populations (women ages 15 and 16 and women ages 14 and below) which Teva’s PBOS exclusivity protects.

It is true that PBOS was originally approved in a dual-packaged configuration that was nonprescription for women ages 17 and over and prescription-only for women ages 16 and below and was held behind the pharmacy counter. As explained above, the product was held behind the

⁴ See Teva’s Cover letter to NDA 021-998, Supplement S-003 at 3 dated June 17, 2013, where they state, without significant analysis, that exclusivity should be granted for “the full OTC product.”

pharmacy counter, not because it was not approved for nonprescription use for women ages 17 and older, but to comply with the prescription dispensing requirements at 503(b) of the Act for women under age 17. It is also true that with the April 30, 2013 and June 20, 2013 approvals of Teva's supplements, PBOS is no longer in a dual nonprescription/prescription package configuration and thus the prescription dispensing requirements in section 503(b) no longer apply. With removal of the prescription labeling, the product now sits on the retail shelf. However, it does not follow that Teva has exclusivity for all nonprescription use of PBOS, nor for its location on the retail shelf.

As described above, Teva received exclusivity for the approval of PBOS for nonprescription use in women 17 and older on July 10, 2009; that exclusivity has expired and FDA has approved ANDAs referencing PBOS for nonprescription use in women 17 and older. PBOS and the ANDAs referencing it were initially approved in the dual prescription/nonprescription packaging configuration. On April 30, 2013, FDA approved S-002 for PBOS for nonprescription use in women ages 15 and 16 with labeling that removed the prescription indication for women ages 14 and below. Teva received exclusivity for S-002 for nonprescription use in 15 and 16 year olds. On June 20, 2013, FDA approved S-003 for PBOS for nonprescription use in women ages 14 and below. Under FDA's "balance exclusivity" policy, nonprescription use of PBOS in women ages 14 and below is protected by the balance of Teva's exclusivity on S-002, because the actual use study submitted in S-002 was also essential to this subsequent approval.

Each of these PBOS approvals involved different regulatory considerations and requirements that influence the conditions under which the product may be marketed. Prior to April 30, 2013, Teva marketed PBOS as nonprescription for women ages 17 and older, and prescription-only for women ages 16 and below. This prescription-only population made the product subject to the prescription dispensing requirements at 503(b) of the Act. With approval of S-002 on April 30, 2013, which provided for nonprescription use of PBOS by 15 and 16 year olds and did not provide for a prescription indication for women of any age, Teva no longer had a prescription version of PBOS. Because Teva had withdrawn the prescription labeling, PBOS was no longer subject to the prescription dispensing requirements in 503(b) and thus could be sold on the retail shelf. With the June 20, 2013 approval of S-003 for nonprescription use of PBOS for women ages 14 and below, FDA approved PBOS, consistent with the court's April 5, 2013 Order, to sit on the retail shelf with no age or point of sale restrictions.⁵ The actual use study submitted by Teva in February 2011 was not the basis for the availability of PBOS for nonprescription use for all ages. That study only showed that PBOS could be used in a nonprescription setting by all women ages 16 and below; FDA had previously approved, and Teva had previously received exclusivity for, PBOS, a one-tablet product for nonprescription use for women ages 17 and older.

Although PBOS may now be sold on the retail shelf because there is no longer a prescription-only requirement for any of the intended population, this does not mean that Teva is entitled to broad exclusivity covering PBOS's status as a nonprescription product for women of *all* ages.

⁵ We note that although PBOS is a nonprescription product and may be available on the retail shelf, because of cost or other considerations, it is possible that a retailer may choose to keep the product behind the sales or pharmacy counter and available upon request.

Rather, Teva has been and should be granted exclusivity incrementally and sequentially for what its studies showed (i.e., that PBOS can be labeled for safe and effective use in a nonprescription setting first by women 17 and older, then by 15 and 16 year old women, and finally by those ages 14 and below), not for the regulatory consequences in terms of packaging or retail availability that may follow from these conclusions.

PBOS Labeling Carve Out

Given that the actual use studies were essential to approval of PBOS for nonprescription use for women ages 16 and below and given that exclusivity covers nonprescription use of PBOS in this population, it follows that the labeling for ANDAs referencing PBOS should carve out nonprescription use of PBOS in this age group. With the carved out labeling, the ANDAs will not be approved for any of the age groups which Teva's actual use study (and Teva's exclusivity) covered. FDA declines to require ANDAs to bear additional labeling on the principal display panel that reinforces the age limit and declines to impose point of sale restrictions on the approved ANDAs. FDA has concluded that additional labeling of the type Teva proposes and any point of sale restrictions to limit actual sales to the various populations are not appropriate, nor are they necessary for safe use of the generic versions of the PBOS product. The labeling protected by Teva's exclusivity does not contain information that is required for safe and effective use of a generic product for the unprotected uses. Therefore, FDA may approve ANDAs referencing PBOS that omit reference in labeling to use by the age groups as to which Teva has exclusivity (i.e., 15 and 16 year old women, and those 14 and below).

Further, restrictive labeling and point of sale restrictions of the type requested by Teva would be inconsistent with how exclusivity for specific populations is generally handled for ANDAs in other contexts. For example, when an innovator's prescription product is granted exclusivity for a new indication, ANDAs approved for the non-protected conditions of use are not required to bear a statement specifically describing the limitations of the approval or to otherwise restrict the use of the generic drug. Similarly, multiple OTC products⁶ lack approval in one or more pediatric populations but no point of sale restrictions apply. There is no scientific or regulatory reason to depart from that approach here.

Attached is sample labeling that appropriately carves out Teva's exclusivity by adding "ages 17 and up" after "for use by women" in both the Directions and Uses section of the Drug Facts box. We have determined that this language is consistent with the scope of Teva's exclusivity under the FD&C Act.

⁶ There are a number of OTC drug products marketed pursuant to the OTC drug review and those approved by FDA in NDAs that have various types of labeling that limit product use to the population for whom the data have established safety and efficacy or for whom the data could be extrapolated. Many products marketed under the OTC drug review are labeled "if under age 2, ask a doctor before use" with similar other age cutoffs at 6 and 12 years for other products. These drugs are available on the retail shelf without sales restrictions that would limit their sale to those for whom they are specifically approved. In addition, other drug products that have switched from Rx to OTC for a particular population have an age limitation with a cutoff for adults only; at 18 years. For example, Prilosec OTC (omeprazole, 20mg), a proton pump inhibitor, includes labeling that says in the Directions section of the drug facts box " * Adults 18 years of age and older" and " * children under 18 years of age: ask a doctor". Moreover, Alli (orlistat, 60 mg) states in the Use section of the drug facts box " * for weight loss in overweight adults, 18 years and older, when used along with a reduced-calorie and low-fat diet" and in the Directions section states " * for overweight adults 18 years and older." These products are thus labeled to limit use to a specific age population, but do not, however, contain a restriction on the sale of the product to those under 18.

Conclusion

For all of these reasons, FDA concludes that ANDAs referencing PBOS are eligible for approval for women ages 17 and above without point of sale restrictions, but with labeling that carves out Teva's protected uses. The labeling for generic OTC PBOS will not reference use in the patient populations for which Teva has exclusivity.

Sincerely yours,

{ See appended electronic signature page }

Kathleen Uhl, M.D.
Acting Director
Office of Generic Drugs
Center for Drug Evaluation and Research

Attachment: Sample Labeling

Levonorgestrel Tablet, 1.5 mg

Drug Facts

Active ingredient

Levonorgestrel 1.5 mg.....Emergency contraceptive

Purpose

Use for women 17 years of age and older to reduce chance of pregnancy after unprotected sex (if a contraceptive failed or if you did not use birth control)

Warnings

Allergy alert: Do not use if you have ever had an allergic reaction to levonorgestrel

Sexually transmitted diseases (STDs) alert: This product does **not** protect against HIV/AIDS or other STDs

Do not use

- if you are already pregnant (because it will not work)
- for regular birth control

When using this product you may have

■	menstrual changes	■	tiredness	■	breast pain
■	nausea	■	headache	■	vomiting
■	lower stomach (abdominal) pain	■	dizziness		

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

- **women 17 years of age or older:**
 - **take as soon as possible within 72 hours (3 days) after unprotected sex. The sooner you take it the better it will work.**
 - **if you vomit within 2 hours after taking the medication, call a healthcare professional to find out if you should repeat the dose**

Other information

- **read the instructions, warnings, and enclosed product leaflet before use**
- this product works mainly by preventing ovulation (egg release). It may also prevent fertilization of a released egg (joining of egg) or attachment of a fertilized egg to the uterus (implantation).
- **do not use if carton is open or tear strip is removed or blister seal is broken or missing**
- store at 20-25°C (68-77°F)

Inactive ingredients

Questions or comments?

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/s/

KATHLEEN UHL
02/25/2014