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On Drugs and Therapeutics

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IN BRIEF

An Oral Contraceptive with Folate

Six years after an FDA advisory committee recommended development of a combination tablet containing an oral contraceptive and folic acid,¹ the FDA has approved *Beyaz* (Bayer), a combination of the oral contraceptive *Yaz*² with 451 mcg of levomefolate calcium, the primary metabolite of folic acid.³ According to the FDA, an unpublished double-blind, randomized U.S. trial in 379 healthy women 18-40 years old found that the combination increased serum folate levels. In an unpublished German study using a similar oral contraceptive/levomefolate combination (summarized in the package insert), folate levels remained elevated for several weeks after levomefolate was stopped.⁴

Table 1. *Beyaz* Components

Product	Formulation	Cost ¹
<i>Beyaz</i> ²	24 tablets: 3 mg drospirenone + 20 mcg ethinyl estradiol + 451 mcg levomefolate calcium 4 tablets: 451 mcg levomefolate calcium	\$1107.60

1. Cost of 13 28-day packs based on AWP listings from *Price Alert* (November 15, 2010). Price is the same for *Yaz*, which contains the same oral contraceptive components without levomefolate calcium. Generic *Yaz* costs \$920.57 for 13 packs.
2. FDA-approved to prevent pregnancy, treat symptoms of premenstrual dysphoric disorder, treat acne and raise folate levels in women who choose to use an oral contraceptive for contraception.

The standard US diet provides 50-500 mcg of absorbable folate per day, but the bioavailability of folate in mixed diets varies. Folic acid in supplements is more bioavailable than folate in food.⁵ Supplementing the diet of women of childbearing age with 400 mcg of folic acid per day, the amount contained in most multivitamin preparations, has dramatically decreased the incidence of neural tube defects in their offspring. To effectively prevent neural tube defects, folic acid supplementation should be started at least one month before conception and continued through the first 2-3 months of pregnancy. Since incorrect or inconsistent use of oral contraceptives may account for as many as one million pregnancies in the US each year, all women capable of becoming pregnant should take a folic acid supplement.^{6,7}

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4. FDA approves combination contraceptive containing a folate. <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm227237.htm>. Accessed October 5, 2010.
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6. Folic acid for the prevention of neural tube defects: U.S. Preventive Services Task Force recommendation statement. *Ann Intern Med* 2009; 150:626.
7. AM Kaunitz. Oral contraceptive use, pregnancy intendedness and folic acid intake. FDA Advisory Committee for Reproductive Health Drugs meeting; December 15, 2003; Gaithersburg, MD. Available at <http://www.fda.gov/ohrms/dockets/ac/03/transcripts/4002T1.DOC>. Accessed November 3, 2010.

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