



# Preferred Drug List

## NEW DRUG REVIEW

**Proprietary Name:** Beyaz™

**Common Name:** drospirenone (DRSP)/ethinyl estradiol (EE)/levomefolate calcium

**PDL Category:** Contraceptives- Monophasic Combination O/C's

<u>Comparable Products</u>	<u>Preferred Drug List Status</u>
Yasmin®	Preferred

### Summary

**Indications and Usage:** Prevention of Pregnancy. Treatment of premenstrual dysphoric disorder (PMDD). Treatment of moderate acne. Folate supplementation for the purpose of reducing the risk of neural tube defect in a pregnancy conceived while taking this product or shortly after discontinuing this product. <sup>1</sup>

**Mechanism of Action:** Suppresses ovulation, modifies cervical mucus and endometrium. <sup>1</sup>

**Dosage Forms:** Tablets; 24 tablets containing 3mg DRSP, 0.02mg EE, and 0.451mg levomefolate calcium and 4 tablets containing 0.451 levomefolate calcium. <sup>1</sup>

**Recommended Dosage:** 1 tablet by mouth once daily <sup>1</sup>

**Common Adverse Drug Reactions:** Menstrual irregularities, headache/migraine, nausea and vomiting, and breast pain/tenderness. <sup>1</sup>

**Contraindications:** A high risk of arterial or venous thrombotic diseases, undiagnosed abnormal uterine bleeding, breast cancer or other estrogen- or progestin-sensitive cancer, liver tumors or liver disease, pregnancy, renal impairment, or adrenal insufficiency. <sup>1</sup>

**Manufacturer:** Bayer Pharmaceuticals, Inc.

**Analysis:** Beyaz™ is the first oral contraceptive containing daily doses of folate. Beyaz™ merges the oral contraceptive Yaz® with a daily dose folate in the form of levomefolate calcium. Safety and efficacy data for contraception, PMDD, and acne indications were obtained from previous Yaz® clinical trials. Two trials were conducted for the folate supplementation indication with plasma and red blood cell (RBC) folate levels being the co-primary endpoints. For the first folate supplementation trial, Yaz® plus levomefolate calcium was compared to Yaz®. Yaz® plus levomefolate calcium increased plasma folate levels to 61nmol/L compared to 41nmol/L with the Yaz® group. In the second trial, Yasmin® was combined with levomefolate calcium or an equimolar dose of folic acid for 24 weeks followed by a 20 week elimination phase of Yasmin® only. Yasmin® plus levomefolate calcium raised plasma folate levels to over 50nmol/L and dropped to baseline at the end of the elimination period. Preferred alternatives, including folic acid, exist on the PDL with similar efficacy and that are more cost effective. Therefore, it is recommended that Beyaz™ be added to the Preferred Drug List as a non-preferred drug.

**IME Recommendation:**

<input type="checkbox"/> Preferred Drug	<input type="checkbox"/> Recommended Drug
<input checked="" type="checkbox"/> Non-Preferred Drug	<input type="checkbox"/> Non-Recommended Drug
<input type="checkbox"/> Non-Preferred Drug with Conditions	

1. Beyaz™ [package insert]. Wayne, NJ: Bayer HealthCare Pharmaceuticals, Inc.; 2010.