

RGH Pharmacy E-Bulletin

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A joint initiative of the Patient Services Section and the Drug and Therapeutics Information Service of the Pharmacy Department, Repatriation General Hospital, Daw Park, South Australia. The RGH Pharmacy E-Bulletin is distributed in electronic format on a weekly basis, and aims to present concise, factual information on issues of current interest in therapeutics, drug safety and cost-effective use of medications.

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Yaz[®] - oral contraceptive for premenstrual dysphoric disorder

Yaz[®] is a new, low dose, combined oral contraceptive (COC) pill that was introduced to the Australian market at the beginning of September 2008. Each tablet contains 20 mcg of ethinylestradiol and 3 mg of drospirenone. This preparation is similar to Yasmin[®] which has been available in Australia for six years; however, Yasmin[®] contains 30 mcg of ethinylestradiol and 3 mg of drospirenone.

Yaz[®] is indicated for use as an oral contraceptive; for the treatment of moderate acne vulgaris in women who seek oral contraception; and it is the first COC approved for the treatment of premenstrual dysphoric disorder (PMDD) in women who seek oral contraception.

PMDD is a severe form of premenstrual syndrome that affects 3–8% of women of reproductive age. It is characterised by a combination of mood swings, depressed mood, irritability or anxiety, which may be accompanied by physical symptoms. These symptoms occur during the luteal phase of the menstrual cycle, and remission generally occurs within three days after the onset of the menses. Specific diagnostic criteria for PMDD are outlined in the *Diagnostic and Statistical Manual of Mental Disorders* (4th edition).

Yaz[®] is unlike other COC products available on the Australian market, as an active pill is taken for 24 days (instead of 21 days) followed by four days of inactive pills. This 24/4 regimen and dosage is associated with greater suppression of follicle development and creates a more stable hormonal levels such that there is less hormonal fluctuation throughout the menstrual cycle. Women will have a monthly withdrawal bleed which is lighter in flow and of shorter duration compared with the 21/7 regimen.

A recent Cochrane systematic review found two placebo-controlled trials that assessed the 24/4 regimen of 20 mcg of ethinylestradiol and 3 mg of drospirenone in women with PMDD. One trial randomised 64 women to either COC or placebo. The second trial was larger and randomised 450 women to either COC or placebo. Women in the treatment group showed less severe premenstrual symptoms after three months in the COC group compared with placebo. Improvements occurred in both mood and physical symptoms. However, it is important to note that a powerful placebo effect was evident in these trials, and nausea, intermenstrual bleeding and breast pain occurred more frequently in the COC group.

At this stage, the effectiveness and safety of such a regimen for PMDD beyond three menstrual cycles is unknown. In addition, little evidence exists for the treatment of less severe premenstrual symptoms. Trials comparing this regimen to other COCs or established treatments for PMDD (e.g. selective serotonin reuptake inhibitors) for efficacy and safety are lacking. Therefore, the long term safety (including effects on the endometrium) and efficacy of this regimen for PMDD is unknown, and further well designed clinical trials are warranted.

Yaz[®] is not available for subsidised supply through the Pharmaceutical Benefits Scheme. For further information regarding drospirenone, please refer to RGH Pharmacy E-Bulletin volume 7(9): October 7, 2002.

The website www.understandingyou.com.au is useful for women to track their menstrual cycle and premenstrual symptoms.

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FOR FURTHER INFORMATION – CONTACT THE PHARMACY DEPARTMENT ON 82751763 or email: chris.alderman@rgh.sa.gov.au
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