

# NEW DRUG EVALUATION

No. 53

January 2003

## YASMIN

Yasmin® is a combined oral contraceptive (ethinylestradiol 30 mcg / drospirenone 3 mg). It has similar contraceptive efficacy and cycle control to other combined oral contraceptives. There is no compelling evidence that its effects on skin, premenstrual symptoms, and feelings of well being are any different to standard combined oral contraceptives. A clinically important effect on weight gain has not been demonstrated. In view of its significantly higher cost its use over other combined oral contraceptives cannot be recommended.

### *What is it?*

Yasmin® is a combined oral contraceptive containing ethinylestradiol 30 mcg and drospirenone 3 mg. Drospirenone is derived from the aldosterone antagonist spironolactone and its pharmacological properties are similar to those of natural progesterone. It is claimed to cause no weight gain, have beneficial effects on the skin, positive effects on premenstrual symptoms and feelings of well being.

### *How effective is it?*

There are two open label comparative studies with Marvelon®, a formulation that contains the same oestrogen combined with desogestrel, a third-generation progestogen. In the first study lasting for 26 cycles (n=887) there were 3 pregnancies in each group and all were thought to be due to user rather than method failure.<sup>1</sup> In the second study 2069 women were randomised in a ratio of 4:1 to either Yasmin® or Marvelon® for 13 cycles. There were 10 pregnancies in the Yasmin® group compared with one in the Marvelon® group.<sup>2</sup> No statistical significance is given. Of these 11 pregnancies only one, in the Yasmin® group, was considered by the authors to be due to method failure. When corrected for other factors (missed tablets, diarrhoea, etc) the number of pregnancies per 100 woman-years use was 0.07 with Yasmin® and 0.28 with Marvelon®. This is reported to be similar to other oral contraceptives.<sup>3</sup>

The frequency and pattern of intermenstrual bleeding, withdrawal bleeding, amenorrhoea and premenstrual symptoms were similar in recipients of Marvelon® and Yasmin® in both studies.<sup>1,2</sup>

### *Weight*

In the 13 cycle study mean weight loss during treatment was statistically significantly greater with Yasmin® than with Marvelon® although the difference was very small

(0.46 kg vs 0.19 kg p<0.0072). In the 26 cycle study the authors report a significant difference between the two groups although no actual figures are presented.<sup>1</sup> In both studies most women maintained a stable body weight (+/- 2 kg).<sup>1,2</sup>

It is not clear from either report whether the results are for all women or only those who completed the study. In both studies women measured their own weight at home and knew which preparation they were taking therefore bias cannot be excluded.

In a small (n=80) dose ranging, open study a significant but small difference on weight was observed after 6 cycles between women taking Microgynon 30® (levonorgestrel 150 mcg, ethinylestradiol 30 mcg) compared with Yasmin® although no p value is given (+ 0.68 kg vs - 0.78 kg).<sup>4</sup>

### *Skin*

In the 13 cycle study the incidence and severity of acne was reduced in both groups from 21.5% to 7.8% in the Yasmin® group and from 20.1% to 8.2% in the Marvelon® group.<sup>2</sup> No statistical difference was reported. Subjects were not selected on the basis of their skin condition.

In a double blind randomised comparative study over 9 cycles in 128 women with mild to moderate acne, the median acne lesion count decreased to a similar extent in women receiving Yasmin® 62.5% and those receiving Dianette® 58.8% (cyproterone 2 mg and ethinylestradiol 35 mcg).<sup>5</sup>

### *How safe is it?*

Discontinuation rates were similar between groups and were around 20%<sup>2</sup> and 30%<sup>1</sup> for each study. 7 - 11% of women withdrew due to adverse events, most frequently headache, menstrual disorders, nausea/vomiting and weight gain.

There have been reports of venous thromboembolism among women taking Yasmin® but the risk compared with other agents is not currently known.<sup>6,7</sup>

#### What other options are there?

Choice of a suitable combined oral contraceptive from the many available involves consideration of safety, side effects, potential drug interactions and cost.<sup>8</sup>

Preparations containing desogestrel and gestodene are associated with a slightly increased risk of venous

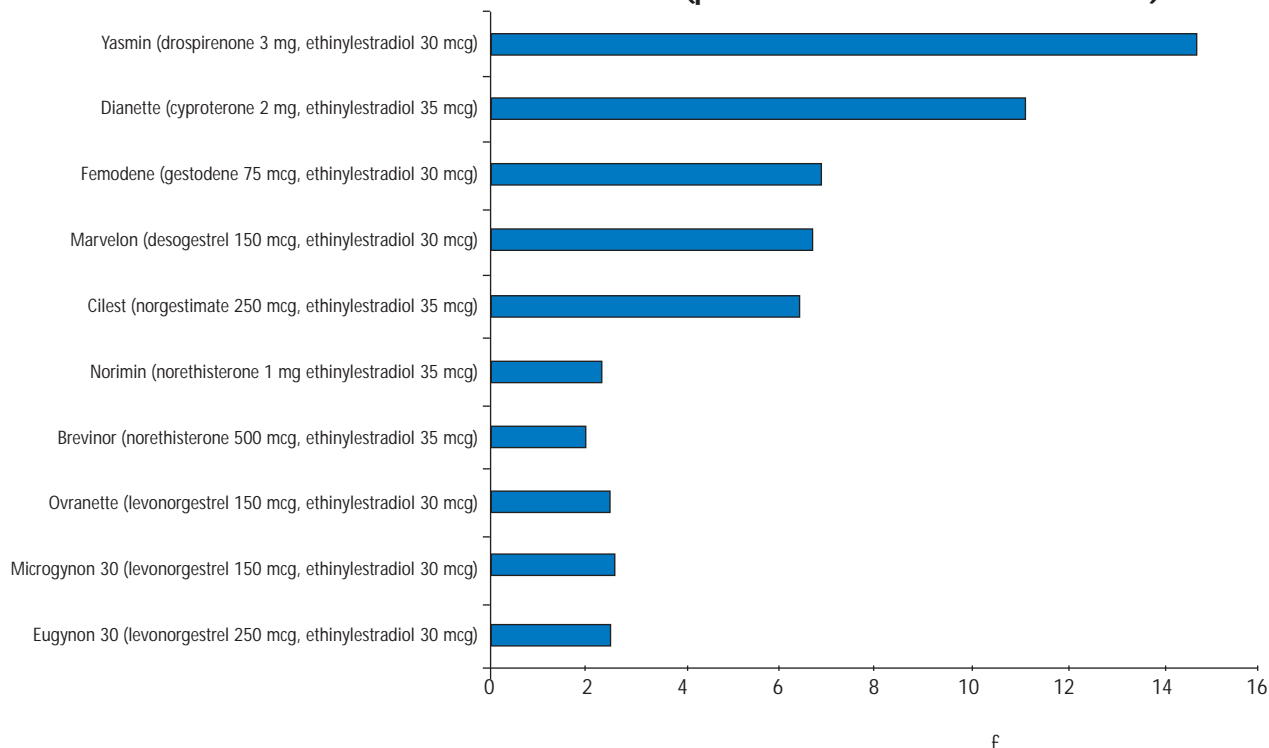
thromboembolism compared to preparations containing levonorgestrel.<sup>9</sup>

#### When should it be used?

There is no evidence that Yasmin® is more effective or better tolerated than more established combined oral contraceptives. A clinically important effect on weight gain has not been demonstrated. In view of its significantly higher cost its use over standard combined oral contraceptives cannot be recommended.

#### How much does it cost?

Cost of 3 months treatment (prices from MIMS December 2002)



#### REFERENCES

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KEY RCT - randomised controlled trial, CT-controlled trial, O-open study, MA-meta analysis, R-review, U-unpublished, A- abstract, E-editorial

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