



CEDAC FINAL RECOMMENDATION and REASONS for RECOMMENDATION

DROSPIRENONE / ETHINYL ESTRADIOL (Yasmin® – Berlex Canada Inc.)

Description:

Yasmin® is a monophasic combination of drospirenone 3 mg and ethinyl estradiol 0.03 mg, approved for oral conception control.

Recommendation:

The Canadian Expert Drug Advisory Committee (CEDAC) recommends that the combination of drospirenone 3 mg and ethinyl estradiol 0.03 mg be listed.

Reasons for the recommendation:

1. Efficacy is similar to currently available monophasic combination oral contraceptives with different progestogen but same ethinyl estradiol concentration.
2. Safety appears to be similar to currently available monophasic combination oral contraceptives with different progestogen but same ethinyl estradiol concentration.
3. Cost is similar compared to currently available monophasic combination oral contraceptives with different progestogen but same ethinyl estradiol concentration.

Of Note:

1. Drospirenone is a new progestogen. In a pooled analysis of randomized trials, patients receiving Yasmin® had, on average, less weight gain than women on the comparator oral contraceptive (a difference of 0.29 kg). Other than this, there is little clinical evidence that mineralocorticoid antagonism or antiandrogenic effects of drospirenone at this dose set it apart from other progestogens used in currently available monophasic combination oral contraceptives.
2. The long-term safety of any new progestogen merits ongoing vigilance, particularly for thromboembolic disease, after it is on the market.
3. Both published and unpublished data were reviewed and taken into consideration in making this recommendation.

Common Drug Review

