

CHANGING FROM PROVERA TO FARLUTAL

Pharmacia Ltd state that the reason they market two products containing medroxyprogesterone acetate for hormone dependent tumours is that, prior to the merger of the two companies, each had its own product. Provera originates from the former Upjohn company and Farlutal originates from Farmitalia Carlo Erba which then became part of Pharmacia. After the merger, both products were retained [1].

Pharmacia stated that there are continuing delays in the supply of Provera and that these may continue to May or June 2001. Notices have been sent to MIMS, Chemist and Druggist and the Pharmaceutical Journal and these should appear shortly [1].

Although both Provera tablets 100mg, 200mg and 400mg and the Farlutal 100mg and 500mg contain the same active constituent (medroxyprogesterone acetate) and are both licensed for the treatment of hormone-sensitive malignancies, formulation of the two brands does differ [2,3].

Published studies [4,5,6] suggest that Provera and Farlutal formulations are unlikely to be bioequivalent. Although no data are available on the relative bioavailability of the 100mg tablets, one study[4] has shown that Farlutal 500mg tablets are about 30% less bioavailable than Provera 500mg tablets.

Until the supply situation for Provera is resolved, the company are advising that if patients are being changed from Provera to Farlutal, these should be regarded as two separate products and the respective data sheet doses should be followed (see table attached). They are aware that some hospitals are making approximate conversions - i.e. for a patient with breast cancer on Provera 600mg daily (midpoint of dosage scale) this would approximate to 1250mg daily of Farlutal.

If such a proportionate conversion is made, it would be necessary to monitor response and adjust the dose accordingly since there are no data to support equivalence.

**PRODUCT COMPARISON OF ORAL PROVERA VS FARLUTAL FOR HORMONE
DEPENDENT MALIGNANCIES**

	PROVERA [3]	FARLUTAL [2]
Presentation	Tablets of 100, 200 or 400mg medroxyprogesterone acetate	Tablets of 100, 250 or 500mg medroxyprogesterone acetate
Excipients	Lactose, crospovidone, polyvinyl pyrrolidone, Polysorbate 80, microcrystalline cellulose, magnesium stearate	Microcrystalline cellulose, Maize starch, byco C, polyethylene glycol, sodium starch glycollate, docusate sodium, sodium benzoate , magnesium stearate
Licensed indications and doses	<ul style="list-style-type: none"> • Breast carcinoma: 400-800 mg daily <p>Doses of up to 1000mg daily have been given although incidence of minor side-effects increases with dose</p> <ul style="list-style-type: none"> • Endometrial and renal carcinoma : 200-400mg daily 	<ul style="list-style-type: none"> • Breast carcinoma : 1000-1500mg daily <p>Doses of up to 2000mg daily have been used</p> <ul style="list-style-type: none"> • Other hormone dependent malignancies : 100-500mg daily

References

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