

A pharmaceutical composition comprising as a first active ingredient an estrogen, such as estradiol or estradiol valerate, in sufficient amounts to treat disorders and symptoms associated with deficient endogenous levels of estrogen in women, and as a second active ingredient 6β , 7β , 15β , 16β -dimethylene-3-oxo- 17α -preg-4-ene-21,17-carbolactone (drospirenone, DRSP) in sufficient amounts to protect the endometrium from the adverse effects of estrogen is useful for, amongst others, treating peri-menopausal, menopausal and post-menopausal women. This composition may be used for hormone replacement therapy and may be administered as a multi-phased pharmaceutical preparation. This combination therapy may comprise continuous, sequential or interrupted administration, or combinations thereof, of DRSP and estrogen, each optionally in micronized form.