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ACTION

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(54) Title: PHARMACEUTICAL COMPOSITIONS COMPRISING ONE OR MORE STEROIDS ONE OR MORE TETRAHYDROFOLATE COMPONENTS AND VITAMIN B12

(57) Abstract: The present invention is concerned with a kit for use in a hormonal contraceptive method or hormone replacement therapy in mammalian females, said kit comprising at least 10 oral dosage units containing at least 1 μg of one or more steroids selected from the group consisting of estrogens and progestogens; at least 0.1 mg of one or more tetrahydrofolate components selected from the group consisting of (6S)-tetrahydrofolic acid, 5-methyl-(6S)-tetrahydrofolic acid, 5-formyl-(6S)-tetrahydrofolic acid, 10-formyl-(6R)-tetrahydrofolic acid, 5,10-methylene-(6R)-tetrahydrofolic acid, 5,10-methenyl-(6R)-tetrahydrofolic acid, 5 formimino-(6S)-tetrahydrofolic acid, pharmaceutically acceptable salts of these tetrahydrofolic acids and glutamyl derivatives of these tetrahydrofolic acids; and at least 0.1 mg vitamin B 12. Other aspects of the present invention relate to a hormonal contraceptive method and a method of hormone replacement therapy comprising the at least once daily oral administration of one or more steroid containing dosage units to a mammalian female, wherein the dosage units additionally contain at least 0.1 mg of one or more of the aforementioned tetrahydrofolate components and at least 0.1 mg vitamin B 12.