CLAIMS

~~1. A method of contraception in a female mammal comprising administering to a female mammal an effective amount of an estetrol component as the estrogeneic component in a combined oral contraceptive (COC) and an effective amount of drospirenone as the progestogenic component.~~

~~2~~1. A composition for use in a method of contraception in a female mammal having a risk of venous thromboembolism (VTE) lower than the VTE risk associated with a 2nd generation combined oral contraceptive (COC), wherein said composition comprises ~~an effective amount~~15 mg to 25 mg of an estetrol component as the estrogen~~e~~ic component in a ~~combined oral contraceptive (~~COC~~)~~ and 0.5 mg to 10 mg ~~an effective amount~~ of drospirenone as the progestogenic component.

~~3~~2. 15 mg to 25 mg ~~An effective amount~~ of an estetrol component for use as the estrogenic component in a combined oral contraceptive (COC) having a risk of venous thromboembolism (VTE) lower than the VTE risk associated with a 2nd generation COC comprising 0.5 mg to 10 mg ~~an effective amount~~ of drospirenone as the progestogenic component.

~~4~~3. Use of a composition ~~for~~ in the manufacture of a medicament for use in a method of contraception in a female mammal having a risk of venous thromboembolism (VTE) lower than the VTE risk associated with a 2nd generation combined oral contraceptive (COC), wherein said composition comprises 15 mg to 25 mg ~~an effective amount~~ of an estetrol component as the estrogen~~e~~ic component in a ~~combined oral contraceptive (~~COC~~)~~ and 0.5 mg to 10 mg ~~an effective amount~~ of drospirenone as the progestogenic component.

~~5~~4. ~~A method according to claim 1, a~~The composition for use according to claim ~~2~~1, 15 mg to 25 mg ~~an effective amount~~ of an estetrol component for use according to claim ~~3~~2, or the use according to claim ~~4~~3, wherein the number, frequency and/or severity of VTE events is reduced compared to other ~~contraceptive methods~~COCs.

~~6. A method, use, composition for use or effective amount of an estetrol component for use according to any one of claims 1 to 5, wherein the venous thromboembolism (VTE) risk is similar to the VTE risk associated with a 2nd generation COC.~~

~~7. A method, use, composition for use or effective amount of an estetrol component for use according to any one of claims 1 to 5, wherein the venous thromboembolism (VTE) risk is similar to the VTE risk during use of a COC based on levonorgestrel, norgestimate or norethisterone, preferably a COC based on levonorgestrel.~~

~~8~~5. ~~A method, use,~~The composition for use, 15 mg of 25 mg ~~or effective amount~~ of an estetrol component for use, or the use according to any one of claims 1 to ~~7~~4, wherein the number of VTE cases is less than 10, preferably less than 8, more preferably less than 7, even more preferably less than 6, yet even more preferably less than 5, yet even more preferably less than 4 per 10,000 women during one year.

~~9. A method, use, composition for use or effective amount of an estetrol component for use according to any one of claims 1 to 8, wherein the estetrol component is used at a daily dose of from 1 mg to 40 mg, preferably at a daily dose of from 5 mg to 25 mg, more preferably at a daily dose from 10 mg to 20 mg, even more preferably at a daily dose of about 15 mg.~~

~~10~~6. ~~A method, use,~~The composition for use, 15 mg to 25 mg ~~or effective amount~~ of an estetrol component for use, or the use according to any one of claims 1 to ~~9~~5, wherein drospirenone is used ~~at a daily dose of from 0.5 mg to 10 mg, preferably~~ at a daily dose of from 1 mg to 4 mg, ~~more~~ preferably at a daily dose of about 3 mg.

~~11~~7. ~~A method, use,~~The composition for use, 15 mg to 25 mg ~~or effective amount~~ of an estetrol component for use, or the use according to any one of claims 1 to ~~6~~10, wherein the administration method is a combined method with an

administration-free interval of about 7 days, ~~preferably~~ or with an administration-free interval of about 4 days.

~~12~~8. ~~A method, use,~~The composition for use, 15 mg to 25 mg ~~or effective amount~~ of an estetrol component for use, or the use according to any one of claims 1 to ~~11~~7, wherein the estetrol component is estetrol, preferably estetrol monohydrate.

~~13~~9. ~~A method, use,~~The composition for use, 15 mg to 25 mg ~~or effective amount~~ of an estetrol component for use, or the use according to claim ~~12~~8, wherein estetrol is used at a daily dose of about 15 mg of estetrol.

~~14~~10. ~~A method, use,~~The composition for use, 15 mg to 25 mg ~~or effective amount~~ of an estetrol component for use, or the use according to claim ~~13~~9, wherein drospirenone is used at a daily dose of about 3 mg.

~~15~~11. ~~A method, use,~~The composition for use, ~~–~~15 mg to 25 mg ~~or effective amount~~ of an estetrol component for use, or the use according to any one of claims 1 to ~~14~~10, wherein the contraceptive is formulated as an oral dosage unit, preferably wherein the dosage unit is formulated to correspond to a daily dosage unit.

~~16~~12. ~~A method, use,~~The composition for use, 15 mg to 25 mg ~~or effective amount~~ of an estetrol component for use, or the use according to any one of claims 1 to ~~15~~11, wherein the haemostatic changes are smaller than the haemostatic changes associated with a 2nd, 3th or 4th generation COC, preferably wherein the haemostatic changes are smaller than the haemostatic changes associated with a 2nd generation COC.

~~17. A method, use, composition for use or effective amount of an estetrol component for use according to any one of claims 1 to 16, wherein the VTE risk is lower than the VTE risk associated with a 3th or with a 4th generation COC, preferably wherein the VTE risk is lower than the VTE risk associated with a 2nd generation COC, more preferably~~

~~wherein the VTE risk is lower than the VTE risk associated with a COC based on levonorgestrel, norgestimate or norethisterone, even more preferably wherein the VTE risk is lower than the VTE risk associated with a COC based on levonorgestrel.~~

~~18~~13. ~~A method, use,~~The composition for use, 15 mg to 25 mg ~~or effective amount~~ of an estetrol component for use, or the use according to any one of claims 1 to ~~17~~12, wherein the profile of side effects other than VTE is better than the profile of side effects associated with a 2nd generation COC.

~~19~~14. ~~A method, use,~~The composition for use, 15 mg to 25 mg ~~or effective amount~~ of an estetrol component for use, or the use according to any one of claims 1 to ~~18~~13, wherein the estetrol component and drospirenone are administered to a woman who is a first-ever user, or a woman who is a switcher or a re-starter with a break of greater than 4 weeks, or a woman with increased baseline risk for VTE due to one or more major risk factors selected from BMI greater than 30, older age, and positive personal and/or family history.

~~20~~15. ~~A method, use,~~The composition for use, ~~–~~15 mg to 25 mg ~~or effective amount~~ of an estetrol component for use, or the use according to any one of claims 1 to ~~19~~14, wherein the relative VTE risk, by comparison to a woman not using COCs, is lower than 3.5, preferably lower than 3.2, more preferably lower than 3.0, even more preferably lower than 2.5, yet even more preferably lower than 2.0.

~~21~~16. ~~A method, use,~~The composition for use, 15 mg to 25 mg ~~or effective amount~~ of an estetrol component for use, or the use according to any one of claims 1 to ~~20~~15, wherein the percentage of subjects in the high risk category for thrombosis, defined as subjects having an odds ratio of 2 or above for thrombosis risk compared to subjects not using COCs, represents less than 40%, preferably less than 35%, more preferably less than 30%, even more preferably less than 25%, yet even more preferably less than 20%, of the total population using said COC.