Claims

1. Use of a composition comprising from 15 mg to 25 mg estetrol and from 1 to 4 mg drospirenone in the manufacture of a medicament for oral contraception, wherein said composition is to be administered to a subject, wherein said composition does not result in haemostatic changes exceeding the boundaries of the normal haemostatic range in said subject such that the number of venous thromboembolism (VTE) cases is less than 5 per 10,000 women during one year, and wherein the normal haemostatic range is defined as the prediction interval that 95% of the population fall into and is determined based on any one or more of the following markers: Sex Hormone Binding Globulin (SHBG), free Tissue Factor Pathway Inhibitor (free TFPI), free and total Protein-S, Protein-S activity, Corticosteroid Binding Globulin (CBG), Ceruloplasmin, antithrombin III, Activated Protein C (APC) resistance, protein-C activity, D-dimer, Prothrombin, Prothrombin fragment 1+2, Factor VII, Factor VIII, von Willebrand factor, Factor II, Plasminogen Activator Inhibitor type- I (PAI-I), tissue-type plasminogen (t-PA), plasminogen, E-selectin and fibrinogen.

2. The use according to claim 1, for preventing risk increase of developing VTE in a subject compared to other combined oral contraceptives (COCs).

3. Use of a combined oral contraceptive in the manufacture of a medicament for avoiding haemostatic changes exceeding the boundaries of the normal haemostatic range in subjects using said combined oral contraceptive such that the number of venous thromboembolism (VTE) cases is less than 5 per 10,000 women during one year, wherein the combined oral contraceptive comprises from 15 mg to 25 mg estetrol and from 1 to 4 mg drospirenone, and wherein the normal haemostatic range is defined as the prediction interval that 95% of the population fall into and is determined based on any one or more of the following markers: Sex Hormone Binding Globulin (SHBG), free Tissue Factor Pathway Inhibitor (free TFPI), free and total Protein-S, Protein-S activity, Corticosteroid Binding Globulin (CBG), Ceruloplasmin, antithrombin III, Activated Protein C (APC) resistance, protein-C activity, D-dimer, Prothrombin, Prothrombin fragment 1+2, Factor VII, Factor VIII,

von Willebrand factor, Factor II, Plasminogen Activator Inhibitor type- I (PAI-I), tissue-type Plasminogen (t-PA), plasminogen, E-selectin and fibrinogen.

4. The use according to claim 3, for preventing risk increase of developing VTE associated with the use of COC's in subjects using the combined oral contraceptive.

5. The use according to any one of claims 1 to 4, wherein said haemostatic change is determined based on a change in level of Protein-S or free TFPI when compared to the normal haemostatic range.

6. The use according to any one of claims 1 to 5, wherein said haemostatic change is measured after one cycle of treatment, after two cycles of treatment or after three cycles of treatment.

7. The use according to any one of claims 1 to 6, wherein said oral contraceptive comprises from 15 to 20 mg estetrol.

8. The use according to any one of claims 1 to 7, wherein said oral contraceptive comprises about 15 mg estetrol.

9. The use according to any one of claims 1 to 8, wherein said oral contraceptive comprises about 20 mg estetrol.

10. The use according to any one of claims 1 to 9, wherein said oral contraceptive comprises about 3 mg drospirenone.

11. The use according to any one of claims 1 to 10, wherein said estetrol is estetrol monohydrate.

12. The use according to any one of claims 1 to 11, wherein said composition is to be administered during at least 21 days, or during 24 days, respectively followed by an administration-free period of about 7 to 4 days.