Claims

1. A medicament comprising:
   - 5-methyl-(6S)-tetrahydrofolate
   - one or more estrogens, selected from the group of ethinylestradiol, mestranol, quinestranol, estradiol, estrone, estrane, estriol, estetrol and conjugated equine estrogens and/or progestogens,
   - optionally vitamin B_6 and/or vitamin B_2,
   - and pharmaceutically acceptable excipients/carriers

   in the absence of Vitamin B_{12}.

2. The medicament as claimed in claim 1, comprising at least one progestogen selected from the group of levonorgestrel, norgestimate, norethisterone, dydrogesterone, drospirenone, 3-beta-hydroxydesogestrel, 3-ketodesogestrel (= etonogestrel), 17-deacetylnorgestimate, 19-norprogesterone, acetoxypregnenolone, allylestrenol, amgestone, chlormadinone, cyproterone, demegestone, desogestrel, dienogest, dihydrogesterone, dimethisterone, ethisterone, ethynodiol diacetate, fluorogestone acetate, gastrinone, gestodene, gestrinone, hydroxymethylprogesterone, hydroxyprogesterone, lynestrenol (= lynoestrenol), mecirogestone, medroxyprogesterone, megestrol, melengestrol, nomegestrol, norethindrone (= norethisterone), norethynodrel, norgestrel (including d-norgestrel and dl-norgestrel), norgestrienone, normethisterone, progesterone, quingestanol, (17alpha)-17-hydroxy-11-methylene-19-norpregna-4,15-dien-20-yn-3-one, tibolone, trimegestone, algestone-acetophenide, nestorone, promegestone, 17-hydroxyprogesterone esters, 19-nor-17hydroxyprogesterone, 17alpha-

ethynyltestosterone, 17alpha-ethynyl-19-nortestosterone, d-17beta-acetoxy-13beta-ethyl-17alpha-ethynylgon-4-en-3-one oxime or the compounds disclosed in WO 00/66570, especially tanaproget.

3. The medicament as claimed in claim 1 comprising a crystalline calcium salt of 5-methyl-(6S)-tetrahydrofolic acid.

4. The medicament as claimed in claim 1, comprising 5-methyl-(6S)-tetrahydrofolate, drospirenone and ethinylestradiol.

5. The medicament as claimed in claim 4 comprising a daily dose of from 0.1 to 10 mg of 5-methyl-(6S)-tetrahydrofolate.

6. The medicament as claimed in claim 4 comprising a daily dose of from 0.4 to 1 mg of 5-methyl-(6S)-tetrahydrofolate.

7. The medicament as claimed in claim 4 comprising a daily dose of 451 µg of the calcium salt of 5-methyl-(6S)-tetrahydrofolic acid.

8. The medicament as claimed in claim 4 comprising a daily dose of from 0.5 to 5 mg of drospirenone.

9. The medicament as claimed in claim 4 comprising a daily dose of 3 mg of drospirenone.

10. The medicament as claimed in claim 4 comprising a daily dose of from 10 to 50 µg of ethinylestradiol.

11. The medicament as claimed in claim 4 comprising a daily dose of from 10 to 30 µg of ethinylestradiol.

12. The medicament as claimed in claim 4 comprising a daily dose of 20 µg of ethinylestradiol.

13. The medicament as claimed in claim 4 comprising a daily dose of 30 µg of ethinylestradiol.

14. The medicament as claimed in claim 4 comprising
- a daily dose of 451 µg of the calcium salt of 5-methyl-(6S)-tetrahydrofolic acid,
- a daily dose of 3 mg of drospirenone and
- a daily dose of 20 µg of ethinylestradiol.

15. The medicament as claimed in claim 4 comprising
- a daily dose of 451 µg of the calcium salt of 5-methyl-(6S)-tetrahydrofolic acid,
- a daily dose of 3 mg of drospirenone and
- a daily dose of 30 µg of ethinylestradiol.

16. A kit comprising
- at least 20 daily dose units comprising a medicament as claimed in any of the preceding claims and
- at least one daily dose unit comprising 5-methyl-(6S)-tetrahydrofolate, and optionally vitamin B_6 and/or vitamin B_2,
- where the number of all the dose units present in the kit is at least 28 and
- the dose units are disposed so that first the dose units comprising the medicament as claimed in any of the preceding claims, and subsequently the dose units comprising only 5-methyl-(6S)-tetrahydrofolate, are to be taken.

17. The kit as claimed in claim 16 comprising
- 20-30 daily dose units comprising a medicament as claimed in any of claims 1 to 15 and
- 1-10 daily dose units comprising 5-methyl-(6S)-tetrahydrofolate.

18. The kit as claimed in claim 16 comprising
- 21-26 daily dose units comprising a medicament as claimed in any of claims 1 to 15 and
- 2-7 daily dose units comprising 5-methyl-(6S)-tetrahydrofolate
- where the number of all the dose units present in the kit is 28.

19. The kit as claimed in claim 16 comprising
- 21 daily dose units comprising a medicament as claimed in any of claims 1 to 15 and
- 7 daily dose units comprising 5-methyl-(6S)-tetrahydrofolate.

20. The kit as claimed in claim 16 comprising
- 24 daily dose units comprising a medicament as claimed in any of claims 1 to 15 and
- 4 daily dose units comprising 5-methyl-(6S)-tetrahydrofolate.

21 The kit as claimed in claim 16 comprising 451 µg of the calcium salt of 5-methyl-(6S)-tetrahydrofolic acid in each daily dose unit.

22. The use of
- 5-methyl-(6S)-tetrahydrofolate
- one or more estrogens, selected from the group of ethinylestradiol, mestranol, quinestranol, estradiol, estrone, estrane, estriol, estetrol or conjugated equine estrogen and/or progestogens,
- optionally vitamin B_6 and/or vitamin B_2,
- and pharmaceutically acceptable excipients/carriers

in the absence of Vitamin B_{12},
for producing a medicament for reducing the risk of disorders caused by folate deficiency and congenital malformations caused by folate deficiency for at least 6-10 weeks after

termination of previous long-term and continual intake of this medicament.

23. The use as claimed in claim 22, characterized in that the preceding long-term regular intake amounts to at least 30 weeks.

24. The use as claimed in either of claims 22 or 23, where the progestogen is selected from the group of levonorgestrel, norgestimate, norethisterone, dydrogesterone, drospirenone, 3-beta-hydroxydesogestrel, 3-ketodesogestrel (= etonogestrel), 17-deacetylnorgestimate, 19-norprogesterone, acetoxypregnenolone, allylestrenol, amgestone, chlormadinone, cyproterone, demegestone, desogestrel, dienogest, dihydrogesterone, dimethisterone, ethisterone, ethynodiol diacetate, fluorogestone acetate, gastrinone, gestodene, gestrinone, hydroxymethylprogesterone, hydroxyprogesterone, lynestrenol (= lynoestrenol), mecirogestone, medroxyprogesterone, megestrol, melengestrol, nomegestrol, norethindrone (= norethisterone), norethynodrel, norgestrel (including d-norgestrel and dl-norgestrel), norgestrienone, normethisterone, progesterone, quingestanol, (17alpha)-17-hydroxy-11-methylene-19-norpregna-4,15-dien-20-yn-3-one, tibolone, trimegestone, algestone acetophenide, nestorone, promegestone, 17-hydroxyprogesterone esters, 19-nor-17hydroxyprogesterone, 17alpha-ethynyltestosterone, 17alpha-ethynyl-19-nortestosterone, d-17beta-acetoxy-13beta-ethyl-17alpha-ethynylgon-4-en-3-one oxime or the compounds disclosed in WO 00/66570, especially tanaproget.

25. The use as claimed in claim 23 or 24 for reducing the risk of neural tube defects.

26. The use as claimed in claim 23 or 24 for reducing the risk of cardiac defects, in particular ventricular valve defects.

27. The use as claimed in claim 23 or 24 for reducing the risk of malformations of the urinary tract (urogenital defects).

28. The use as claimed in claim 23 or 24 for reducing the risk of cleft lip, jaw and palate.

29. The use as claimed in claim 23 or 24 for reducing the risk of spontaneous abortions.

30. The use as claimed in claim 23 or 24 for reducing the risk of malignant disorders, in particular carcinoma of the breast or colon.

31. The use as claimed in claim 23 or 24 for reducing the risk of cardiovascular disorders.

32. The use of 5-methyl-(6S)-tetrahydrofolate, drospirenone and ethinylestradiol as claimed in claim 25 to 31.

33. The use of 451 µg of the calcium salt of 5-methyl-(6S)-tetrahydrofolic acid, 3 mg of drospirenone and 20 µg of ethinylestradiol as claimed in claim 25 to 31.

34. The use of 451 µg of the calcium salt of 5-methyl-(6S)-tetrahydrofolic acid, 3 mg of drospirenone and 30 µg of ethinylestradiol as claimed in claim 25 to 31.

35. The kit as claimed in claim 16, comprising
- 21 daily dose units comprising a medicament as claimed in claim 14 and

- 7 daily dose units comprising 5-methyl-(6S)-tetrahydrofolate.

36. The kit as claimed in claim 16, comprising
- 24 daily dose units comprising a medicament as claimed in claim 14 and
- 4 daily dose units comprising 5-methyl-(6S)-tetrahydrofolate.

37. The kit as claimed in claim 16, comprising
- 21 daily dose units comprising a medicament as claimed in claim 15 and
- 7 daily dose units comprising 5-methyl-(6S)-tetrahydrofolate.

38. A method for formulating the medicament as claimed in any of claims 1 to 15, characterized in that the 5-methyl-(6S)-tetrahydrofolate is absorbed only after the granulation.

39. The method as claimed in claim 38, characterized in that low-substituted hydroxypropylcellulose is used as binder.

40. The kit as claimed in claim 16, comprising more than 28 daily dose units, where at least 28 daily dose units comprise a medicament as claimed in any of claims 1 to 15, and where at least one daily dose unit comprises 5-methyl-(6S)-tetrahydrofolate, and where the dose units are disposed so that firstly the dose units comprising the medicament as claimed in any of claims 1 to 15, and subsequently the dose units comprising only 5-methyl-(6S)-tetrahydrofolate, are to be taken.

41. The kit as claimed in claim 40, in which the number of dose units comprising a medicament as claimed in any claims 1 to 15 is 28 plus 21, 22,

23, 24, 25, 26 or 27 or an integral multiple of 28 plus 21, 22, 23, 24, 25, 26 or 27, and where the number of daily dose units which comprise only 5-methyl-(6S)-tetrahydrofolate is 7, 6, 5, 4, 3, 2 or 1.

42. The kit as claimed in claim 41, in which the multiple is 2, 3, 4, 5, 6, 7, 8, 9, 10, 11 or 12.

43. A kit comprising more than 28 daily dose units, where at least 28 daily dose units comprise a medicament as claimed in any of claims 1 to 15, where at least one daily dose unit is a placebo or a blank pill day, and where the dose units are disposed so that first the dose units comprising the medicament as claimed in any of claims 1 to 15 are to be taken.

44. The kit as claimed in claim 43, in which the number of dose units comprising as claimed in any of claims 1 to 15 is 28 plus 21, 22, 23, 24, 25, 26 or 27 or an integral multiple of 28 plus 21, 22, 23, 24, 25, 26 or 27, and where the number of placebos or blank pill days is 7, 6, 5, 4, 3, 2 or 1.

45. The kit as claimed in claim 44, in which the multiple is 2, 3, 4, 5, 6, 7, 8, 9, 10, 11 or 12.

46. The kit as claimed in any of claims 40 to 45, in which the dose units comprising medicament comprise a medicament as claimed in claim 14.

47. The kit as claimed in any of claims 40 to 45, in which the dose units comprising medicament comprise a medicament as claimed in claim 15.

Claims

1. A method for formulating a medicament comprising:

a daily dose of 0.4 to 1 mg of 5-methyl-(6S)-tetrahydrofolate;
one or more estrogens and/or progestogens; and
one or more pharmaceutically acceptable excipients/carriers
in the absence of vitamin B12,

wherein the 5-methyl-(6S)-tetrahydrofolate is absorbed only after granulation.

2. A method for formulating a medicament according to Claim 1, wherein the one or more estrogens is selected from the group consisting of ethinylestradiol, mestranol, quinestranol, estradiol, estrone, estrane, estriol, estetrol and conjugated equine estrogens.

3. A method for formulating a medicament according to Claim 1 or Claim 2, wherein the one or more progestogens is selected from the group consisting of levonorgestrel, norgestimate, norethisterone, dydrogesterone, drospirenone, 3-beta-hydroxydesogestrel, 3-ketodesogestrel (= etonogestrel), 17-deacetylnorgestimate, 19-norprogesterone, acetoxypregnenolone, allylestrenol, amgestone, chlormadinone, cyproterone, demegestone, desogestrel, dienogest, dihydrogesterone, dimethisterone, ethisterone, ethynodiol diacetate, fluorogestone acetate, gastrinone, gestodene, gestrinone, hydroxymethylprogesterone, hydroxypregesterone, lynestrenol (lynoestrenol), necirogestone, medroxyprogesterone, megestrol, melengestrol, nomegestrol, norethindrone (norethisterone), norethynodrel, norgestrel, d-norgestrel, dl-norgestrel, norgestrienone, normethisterone, progesterone, quingestanol, (17alpha)-17-hydroxy-11-methylene-19-norpregna-4,15-dien-20-yn-3-one, tibolone, trimegestone, algestone-acetophenide, nestorone, promegestone, 17-hydroxypro-gesterone esters, 19-nor-17hydroxyprogesterone, 17alpha-ethynyltestosterone, 17alpha-ethynyl-19-nortestoster-one, d-17beta-acetoxy-13beta-ethyl-17alpha-ethynylgon-4-en-3-one oxime and tanaproget.

4. A method for formulating a medicament according to any one of Claims 1 to 3, wherein the medicament comprises a crystalline calcium

salt of 5-methyl-(6S)-tetrahydrofolic acid.

5. A method for formulating a medicament according to Claim 1, wherein the medicament comprises 5-methyl-(6S)-tetrahydrofolate, drospirenone and ethinylestradiol.

6. A method for formulating a medicament according to Claim 5, wherein the medicament comprises a crystalline calcium salt of 5-methyl-(6S)-tetrahydrofolic acid at a daily dose of 451 µg.

7. A method for formulating a medicament according to Claim 5 or Claim 6, wherein the medicament comprises a daily dose of 3 mg of drospirenone.

8. A method for formulating a medicament according to any one of Claims 5 to 7, wherein the medicament comprises a daily dose of from 10 to 50 µg of ethinylestradiol.

9. A method for formulating a medicament according to any one of Claims 5 to 7, wherein the medicament comprises a daily dose of from 10 to 30 µg of ethinylestradiol.

10. A method for formulating a medicament according to any one of Claims 5 to 7, wherein the medicament comprises a daily dose of 20 µg of ethinylestradiol.

11. A method for formulating a medicament according to any one of Claims 5 to 7, wherein the medicament comprises a daily dose of 30 µg of ethinylestradiol.

12. A method for formulating a medicament according to Claim 5, wherein the medicament comprises:

a daily dose of 451 µg of the calcium salt of 5-methyl-(6S)-tetrahydrofolic acid;
a daily dose of 3 mg of drospirenone; and
a daily dose of 20 µg of ethinylestradiol.

13. A method for formulating a medicament according to Claim 5, wherein the medicament comprises:

a daily dose of 451 µg of the calcium salt of 5-methyl-(6S)-tetrahydrofolic acid;
a daily dose of 3 mg of drospirenone; and
a daily dose of 30 µg of ethinylestradiol.

14. A medicament formulated by the method of any one of Claims 1 to 13.