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(54) Title: COMPOSITIONS AND METHODS FOR THE TREATMENT OF OSTEOPOROSIS AND INFLAMMATORY JOINT DISEASE

(57) Abstract: Compositions and methods for the treatment of osteoporosis and/or inflammatory joint disease are provided herein. The compositions contain a folate, such as a reduced folate, and folic acid. The folate is preferably 5-methyltetrahydrofolate, and most preferably 5-methyl-(6S)-tetrahydrofolic acid. The folate and folic acid can be given in the same dosage unit or separate dosage units, and more than one dosage unit can be given per dose. The compositions may also contain one or more vitamins and minerals selected from vitamin B 12, vitamin B6, vitamin D3, calcium, magnesium, and polyunsaturated fatty acids (PUFAs). These ingredients are optional, but preferable (especially the vitamins and minerals). The compositions may further contain one or more additional ingredients such as vitamins, minerals, and laxatives. The compositions are useful in the treatment of all forms of osteoporosis, including primary osteoporosis and secondary osteoporosis, and/or inflammatory joint diseases, especially in patients having a folic acid metabolism deficiency. The compositions are particularly useful in the treatment of inflammatory joint diseases, with complications that include bone loss, fracture, and osteoporosis. In addition, the compositions are beneficial for the prevention of osteoporosis in subjects who do not yet have the disease, but who are at risk for getting osteoporosis, such as post-menopausal women, subjects with osteopenia (mid thinning of the bone mass), subjects with an inflammatory joint disease, or people who are over the age of 70.

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# AMENDED CLAIMS
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1. A composition for the treatment or prevention of osteoporosis or inflammatory joint disease comprising a reduced folate, vitamin B12, vitamin B6, vitamin D3, magnesium and calcium in excess of 200 mg.

2. The composition of claim 1, wherein the reduced folate is selected from the group consisting of 5-methyl-(6S)-tetrahydrofolic acid and 5-methyl-(6R,S)-tetrahydrofolic acid.

3. The composition of claim 2, wherein the composition comprises 0.5 mg of 5-methyl-(6S)-tetrahydrofolic acid, 250 micrograms of vitamin B12, 1.2 mg of vitamin B6, 200 IU of vitamin D3, 50 mg of magnesium, and 500 mg of calcium.

4. A method of treating osteoporosis in a patient in need thereof comprising administering a therapeutically effective amount of a reduced folate to the patient.

5. The method of claim 4 wherein the reduced folate is administered in one dosage unit.

6. The method of claim 5, wherein more than one unit is administered per dose.

7. The method of claim 4 further comprising administering a therapeutically effective amount of one or more compounds selected from the group consisting of vitamin B12, vitamin B6, vitamin D3, calcium, magnesium, folic acid, and a polyunsaturated fatty acid or mixture of polyunsaturated fatty acids.

8. The method of claim 4, wherein the reduced folate is selected from the group consisting of 5-methyl-(6S)-tetrahydrofolic acid and 5-methyl-(6R,S)-tetrahydrofolic acid.

9. The method of claim 4, wherein the patient has a folic acid metabolism deficiency.

10. The method of claim 4, wherein the patient has an inflammatory joint disease.

11. A method of preventing osteoporosis in a patient at risk of developing osteoporosis comprising administering a therapeutically effective amount of a reduced folate to the patient.

12. The method of claim 11, wherein the reduced folate is administered in one dosage unit.

13. The method of claim 12, wherein more than one unit is administered per dose.

14. The method of claim 11 further comprising administering a therapeutically effective amount of one or more compounds selected from the group consisting of vitamin B12, vitamin B6, vitamin D3, calcium, magnesium, folic acid and a polyunsaturated fatty acid or mixtures of polyunsaturated fatty acids.

15. The method of claim 11, wherein the reduced folate is selected from the group consisting of 5-methyl-(6S)-tetrahydrofolic acid and 5-methyl-(6R,S)-tetrahydrofolic acid.

16. The method of claim 11, wherein the patient has a folic acid metabolism deficiency.

17. The method of claim 11, wherein the patient is selected from the group consisting of a post-menopausal woman, a subject with osteopenia, a subject with chronic inflammatory joint disease, and a patient over the age of 70.

18. A method of treating a chronic inflammatory joint disease in a patient in need thereof comprising administering a therapeutically effective amount of a reduced folate to the patient.

19. The method of claim 18 further comprising administering a therapeutically effective amount of one or more compounds selected from the group consisting of vitamin B12, vitamin B6, vitamin D3, calcium, magnesium, folic acid, and a polyunsaturated fatty acid or mixture of polyunsaturated fatty acids.

20. The method of claim 18, wherein the disease is selected from the group consisting of rheumatoid arthritis, juvenile rheumatoid arthritis, psoriatic arthritis, Reiter's syndrome, Crohn's disease, ulcerative colitis, and sarcoidosis.