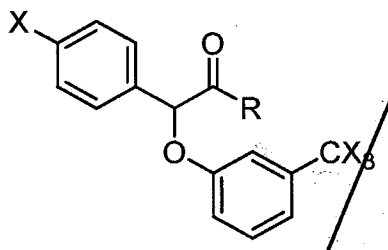
WHAT IS CLAIMED IS:

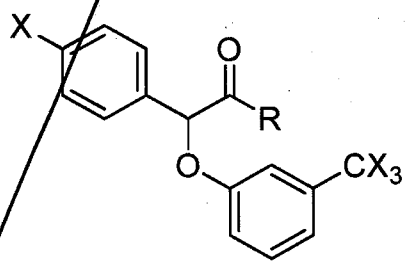
1. A method of lowering the serum uric acid level of a subject with hyperuricemia, the method comprising administering to the subject a first urate-lowering agent and a second urate-lowering agent, wherein the first urate-lowering agent is a compound of Formula (I)



(I)

wherein R is selected from the group consisting of hydroxy, lower aralkoxy, di-lower alkylamino-lower alkoxy, lower alkanamido-lower alkoxy, benzamido-lower alkoxy, ureido-lower alkoxy, N'-lower alkyl-ureido-lower alkoxy, carbamoyl-lower alkoxy, halophenoxy-substituted lower alkoxy, carbamoyl-substituted phenoxy, carbonyl-lower alkylamino, N,N-di-lower alkylamino-lower alkylamino, halo-substituted lower alkylamino, hydroxyl- substituted lower alkylamino, lower alkanolyloxy-substituted lower alkylamino, ureido, and lower alkoxy carbonylamino; and each X is independently a halogen; or a pharmaceutically acceptable salt thereof.

2. A method of treating a subject having a condition associated with hyperuricemia, the method comprising administering to the subject a first urate-lowering agent and a second urate-lowering agent, wherein the first urate-lowering agent is a compound of Formula (I)



(I)

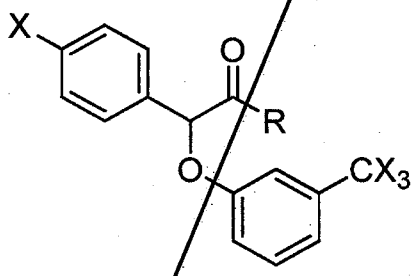
wherein R is selected from the group consisting of hydroxy, lower aralkoxy, di-lower alkylamino-lower alkoxy, lower alkanamido-lower alkoxy, benzamido-lower alkoxy, ureido-lower alkoxy, N'-lower alkyl-ureido-lower alkoxy, carbamoyl-lower alkoxy, halophenoxy-

substituted lower alkoxy, carbamoyl-substituted phenoxy, carbonyl-lower alkylamino, N,N-di-lower alkylamino-lower alkylamino, halo-substituted lower alkylamino, hydroxyl- substituted lower alkylamino, lower alkanolyloxy-substituted lower alkylamino, ureido, and lower alkoxy carbonylamino; and each X is independently a halogen; or a pharmaceutically acceptable salt thereof.

3. The method of Claim 2, wherein the condition associated with hyperuricemia is gout.

4. The method of Claim 3, wherein the condition is acute gout, chronic gout, moderate gout, refractory gout or severe gout.

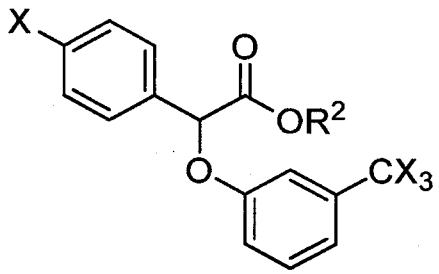
5. A method of treating hyperuricemia in a subject with gout comprising administering to the subject a composition comprising a first urate-lowering agent and a second urate-lowering agent, wherein the first urate-lowering agent is a compound of Formula (I)



(I)

wherein R is selected from the group consisting of hydroxy, lower aralkoxy, di-lower alkylamino-lower alkoxy, lower alkanamido-lower alkoxy, benzamido-lower alkoxy, ureido-lower alkoxy, N'-lower alkyl-ureido-lower alkoxy, carbamoyl-lower alkoxy, halophenoxy-substituted lower alkoxy, carbamoyl-substituted phenoxy, carbonyl-lower alkylamino, N,N-di-lower alkylamino-lower alkylamino, halo-substituted lower alkylamino, hydroxyl- substituted lower alkylamino, lower alkanolyloxy-substituted lower alkylamino, ureido, and lower alkoxy carbonylamino; and each X is independently a halogen; or a pharmaceutically acceptable salt thereof.

6. The method of any one of Claims 1 to 5, wherein the first urate-lowering agent is a compound of Formula (II)



(II)

wherein R^2 is selected from the group consisting of phenyl-lower alkyl, lower alkanamido-lower alkyl and benzamido-lower alkyl, and each X is independently a halogen; or a pharmaceutically acceptable salt thereof.

7. The method of any one of Claims 1 to 6, wherein the first urate-lowering agent is halofenate or halofenic acid, or a pharmaceutically acceptable salt thereof, preferably (-)-halofenate or (-)-halofenic acid, or a pharmaceutically acceptable salt thereof.

8. The method of any one of Claims 1 to 7, wherein the first urate-lowering agent is (-)-halofenate.

9. The method of any one of Claims 1 to 8, wherein the second urate-lowering agent is selected from the group consisting of a xanthine oxidase inhibitor, an inhibitor of uric acid production, a uricosuric agent and a uricase.

10. The method of Claim 9, wherein the second urate-lowering agent is a xanthine oxidase inhibitor, preferably selected from the group consisting of allopurinol, febuxostat, oxypurinol, tisopurine, inositol, phytic acid, myo-inositiol, kaempferol, myricetin, and quercetin, especially allopurinol or febuxostat.

11. The method of Claim 10, wherein the first urate-lowering agent is (-)-halofenate and is administered at from about 100 mg to about 600 mg per day, and the second urate-lowering agent is allopurinol and is administered at from about 50 mg to about 800 mg per day.

12. The method of Claim 10, wherein the first urate-lowering agent is (-)-halofenate and is administered at from about 100 mg to about 600 mg per day, and the second urate-lowering agent is febuxostat and is administered at from about 40 mg to about 120 mg per day.

13. The method of Claim 8, wherein the second urate-lowering agent is a uricosuric agent, preferably selected from the group consisting of probenecid, 2-((5-bromo-4-(4-cyclopropylnaphthalen-1-yl)-4H-1,2,4-triazol-3-yl)thio)acetic acid, potassium 4-(2-((5-bromo-4-(4-cyclopropylnaphthalen-1-yl)-4H-1,2,4-triazol-3-yl)thio)acetamido)-3-chlorobenzoate, RDEA684, benzbromarone, sulfinpyrazone, amlodipine, atorvastatin, fenofibrate, guaifenesin, losartan, adrenocorticotropic hormone and cortisone, especially probenecid.

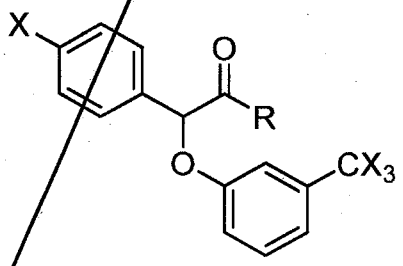
14. The method of anyone of Claims 1 to 13, wherein the subject has experienced insufficient lowering of serum uric acid during or following treatment with one or more second urate-lowering agents but not a first urate-lowering agent.

15. The method of any one of Claims 1 to 13, wherein the subject has a serum uric acid level of about 8 mg/dL or greater.

16. The method of Claim 14 or 15, wherein the subject's serum uric acid level is lowered to about 7 mg/dL or less, preferably to about 6 mg/mL or less.

17. The method of any one of Claims 1 to 16, where at least one of the first urate-lowering agent and second urate-lowering agent is administered orally.

18. A pharmaceutical composition comprising a first urate-lowering agent and a second urate-lowering agent, wherein the first urate-lowering agent is a compound of Formula (I)

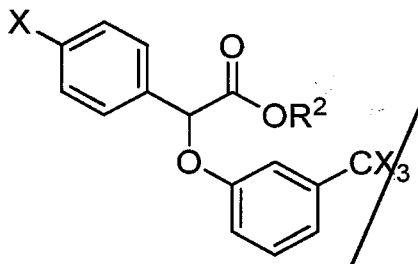


(I)

wherein R is selected from the group consisting of hydroxy, lower aralkoxy, di-lower alkylamino-lower alkoxy, lower alkanamido-lower alkoxy, benzamido-lower alkoxy, ureido-lower alkoxy, N'-lower alkyl-ureido-lower alkoxy, carbamoyl-lower alkoxy, halophenoxy-substituted lower alkoxy, carbamoyl-substituted phenoxy, carbonyl-lower alkylamino, N,N-di-lower alkylamino-lower alkylamino, halo-substituted lower alkylamino, hydroxyl- substituted

lower alkylamino, lower alkanolyloxy-substituted lower alkylamino, ureido and lower alkoxycarbonylamino; and each X is independently a halogen; or a pharmaceutically acceptable salt thereof.

19. The composition of Claim 18, wherein the first urate-lowering agent is a compound of Formula (II)



(II)

wherein R^2 is selected from the group consisting of phenyl-lower alkyl, lower alkanamido-lower alkyl and benzamido-lower alkyl, and each X is independently a halogen; or a pharmaceutically acceptable salt thereof.

20. The composition of Claim 19, wherein the first urate-lowering agent is halofenate or halofenic acid, or a pharmaceutically acceptable salt thereof, preferably (-)-halofenate or (-)-halofenic acid, or a pharmaceutically acceptable salt thereof.

21. The composition of Claim 20, wherein the first urate-lowering agent is (-)-halofenate.

22. The composition of Claim 21, wherein the composition comprises from about 100 mg to about 600 mg of (-)-halofenate.

23. The composition of any one of Claims 18 to 22, wherein the composition comprises from about 50 mg to about 800 mg of the second urate-lowering agent, and wherein the second urate-lowering agent is allopurinol.

24. The composition of any one of Claims 18 to 22, wherein the composition comprises from about 20 mg to about 120 mg of the second urate-lowering agent, and wherein the second urate-lowering agent is febuxostat.

25. The composition of any one of Claims 18 to 24 for oral administration.

26. A kit comprising a composition of any one of Claims 18 to 25, optionally further comprising packaging and instructions for use.

WHAT IS CLAIMED IS:

1. An oral dosage composition comprising:

(a) a compound that is (-)-halofenate, or (-)-halofenic acid or a pharmaceutically acceptable salt thereof, substantially free from the corresponding (+)-enantiomer; and

(b) febuxostat.

2. The composition of claim 1, where the compound is (-)-halofenate, substantially free from the corresponding (+)-enantiomer.

3. The composition of claim 1, where the compound is (-)-halofenic acid or a pharmaceutically acceptable salt thereof, substantially free from the corresponding (+)-enantiomer.

4. The composition of any one of claims 1 to 3 where the amounts of the compound and of the febuxostat together are effective for once/day dosing.

5. The composition of any one of claims 1 to 4 where the amount of the compound is between 10 mg and 1000 mg.

6. The composition of claim 5 where the amount of the compound is between 100 mg and 800 mg.

7. The composition of any one of claims 1 to 6 where the amount of the febuxostat is between 20 mg and 120 mg.

8. The composition of claim 7 where the amount of the febuxostat is between 40 mg and 120 mg.

9. The composition of any one of claims 1 to 8 that is a tablet.

10. The composition of any one of claims 1 to 8 that is a capsule.

11. The composition of any one of claims 1 to 8 that is a syrup.

12. The composition of any one of claims 1 to 8 that is a suspension.

13. The use of a compound that is (-)-halofenate, or (-)-halofenic acid or a pharmaceutically acceptable salt thereof, substantially free from the corresponding (+)-enantiomer, in the manufacture of a medicament for treating hyperuricemia, or for lowering serum uric acid, or for reducing the size or number of tophi, or for treating urate crystal formation, in a subject with gout, where the subject is also administered febuxostat.

14. The use of claim 13, where the compound is (-)-halofenate, substantially free from the corresponding (+)-enantiomer.

15. The use of claim 13, where the compound is (-)-halofenic acid or a pharmaceutically acceptable salt thereof, substantially free from the corresponding (+)-enantiomer.

16. The use of any one of claims 13 to 15 where the amounts of the compound and of the febuxostat together are effective for once/day dosing.

17. The use of any one of claims 13 to 16 where the compound is administered at between 10 mg/day and 1000 mg/day.

18. The use of claim 17 where the compound is administered at between 100 mg/day and 800 mg/day.

19. The use of any one of claims 13 to 18 where the febuxostat is administered at between 20 mg/day and 120 mg/day.

20. The use of claim 19 where the febuxostat is administered at between 40 mg/day and 120 mg/day.

21. The use of any one of claims 13 to 20, where the subject is refractory to febuxostat.

22. The use of any one of claims 13 to 21 where the subject reaches a serum uric acid level of 6.0 mg/dL or less on administration of the compound and the febuxostat.

23. The use of claim 22 where the subject reaches a serum uric acid level of 5.0 mg/dL or less on administration of the compound and the febuxostat.

24. The use of claim 23 where the subject reaches a serum uric acid level of 4.0 mg/dL or less on administration of the compound and the febuxostat.

25. The use of claim 24 where the subject reaches a serum uric acid level of 3.0 mg/dL or less on administration of the compound and the febuxostat.

26. The use of any one of claims 13 to 25, where the gout is severe gout.

27. The use of any one of claims 13 to 25, where the gout is refractory gout.

28. The use of any one of claims 13 to 27 that is for treating hyperuricemia in a subject with gout.

29. The use of any one of claims 13 to 27 that is for lowering serum uric acid in a subject with gout.

30. The use of any one of claims 13 to 27 that is for reducing the size or number of tophi in a subject with gout.

31. The use of any one of claims 13 to 27 that is for treating urate crystal formation in a subject with gout.