CLAIMS

What is claimed:

1. A method for switching a patient who is currently being administered sodium oxybate to a mixed salt oxybate composition, the method comprising:

   administering a therapeutically effective amount of a mixed salt oxybate to a patient who has cataplexy or excessive daytime sleepiness with narcolepsy and is being treated with sodium oxybate, wherein the amount of the sodium oxybate and the mixed salt oxybate are within 10% on an oxybate dosing strength basis.

2. The method of claim 1, wherein the mixed salt oxybate comprises sodium oxybate, potassium oxybate, magnesium oxybate and calcium oxybate, and wherein the mixed salt oxybate comprises about 5%-40% sodium oxybate (wt/wt%).

3. The method of claim 2, wherein the mixed salt oxybate comprises about 5%-40% of sodium oxybate (wt/wt%), about 10%-40% of potassium oxybate (wt/wt%), about 5%-30% of magnesium oxybate (wt/wt%), and about 20%-80% of calcium oxybate (wt/wt%).

4. The method of claim 3, wherein the mixed salt oxybate comprises about 8% mol. equiv. of sodium oxybate, about 23% mol. equiv. of potassium oxybate, about 21% mol. equiv. of magnesium oxybate and about 48% mol. equiv. calcium oxybate.

5. The method of any one of claims 1-4, wherein the patient is sensitive to high sodium intake.

6. The method of any one of claims 1-5, wherein the patient is in heart failure.

7. The method of any one of claims 1-5, wherein the patient is hypertensive.

8. The method of any one of claims 1-5, wherein the patient has renal impairment.

9. The method of any one of claims 1-5, wherein the patient is at risk for stroke.

10. The method of any one of claims 1-9, wherein about 0.25 g-10.0 g, 2.0 g-10.0 g; about 3.0 g-9.5 g; or about 4.5 g-9.0 g of the mixed salt oxybate is administered per day.

11. The method of claim 10, wherein the mixed salt oxybate is administered twice per day.

12. The method of claim 10, wherein the mixed salt oxybate is administered once per day.

13. The method of any one of claims 1-12, wherein about 4.5 g of the mixed salt oxybate is administered per day.

14. The method of claim 13, wherein about 2.25 g of the mixed salt oxybate is administered twice per day.

15. The method of any one of claims 1-12, wherein about 6.0 g of the mixed salt oxybate is administered per day.

16. The method of claim 15, wherein about 3.0 g of the mixed salt oxybate is administered twice per day.

17. The method of any one of claims 1-12, wherein about 7.5 g of the mixed salt oxybate is administered per day.

18. The method of claim 17, wherein about 3.75 g of the mixed salt oxybate is administered twice per day.

19. The method of any one of claims 1-12, wherein about 9.0 g of the mixed salt oxybate is administered per day.

20. The method of claim 19, wherein about 4.5 g of the mixed salt oxybate is administered twice per day.

21. The method of any one of claims 1-20, wherein the mixed salt oxybate composition is a liquid.

22. The method of claim 21, wherein the concentration of the mixed salt oxybate in the liquid is from 350 mg/ml-650 mg/ml, or about 450 mg/ml-550 mg/ml.

23. The method of claim 21, wherein the concentration of the mixed salt oxybate in the liquid is about 0.5 g/mL.

24. The method of any one of claims 1-23, wherein the patient is treated for cataplexy.

25. The method of any one of claims 1-23, wherein the patient is treated for excessive daytime sleepiness in patients with narcolepsy.

26. The method of any one of claims 1-25, wherein the mixed salt oxybate is administered at bedtime.

27. The method of any one of claims 1-26 wherein the mixed salt oxybate is administered at bedtime and about 2.5 h-4 h after the bedtime administration.

28. A method for treating cataplexy or excessive daytime sleepiness in patients with narcolepsy, the method comprising

switching a patient who is administered sodium oxybate to a mixed salt oxybate,
wherein the switching comprises administering a therapeutically effective amount of the mixed salt oxybate to the patient and wherein the amount of sodium oxybate and mixed salt oxybate are within 5% on an oxybate dosing strength basis.

29. The method of claim 28, wherein the mixed salt oxybate comprises sodium oxybate, potassium oxybate, magnesium oxybate and calcium oxybate, and wherein the mixed salt oxybate comprises about 5%-40% sodium oxybate (wt/wt%).

30. The method of claim 29, wherein the mixed salt oxybate comprises about 5%-40% of sodium oxybate (wt/wt%), about 10%-40% of potassium oxybate (wt/wt%), about 5%-30% of magnesium oxybate (wt/wt%), and about 20%-80% of calcium oxybate (wt/wt%).

31. The method of claim 30, wherein the mixed salt oxybate comprises about 8% mol. equiv. of sodium oxybate, about 23% mol. equiv. of potassium oxybate, about 21% mol. equiv. of magnesium oxybate and about 48% mol. equiv. of calcium oxybate.

32. The method of any one of claims 28-31, wherein the patient is sensitive to high sodium intake.

33. The method of any one of claims 28-32, wherein the patient is in heart failure.

34. The method of any one of claims 28-32, wherein the patient is hypertensive.

35. The method of any one of claims 28-32, wherein the patient has renal impairment.

36. The method of any one of claims 28-32, wherein the patient is at risk for stroke.

37. The method of any one of claims 28-36, wherein about 2.0 g-10.0 g; about 3.0 g-9.5 g; or about 4.5 g-9.0 g of the mixed salt oxybate is administered per day.

38. The method of claim 37, wherein the mixed salt oxybate is administered twice per day.

39. The method of claim 37, wherein the mixed salt oxybate is administered once per day.

40. The method of any one of claims 28-39, wherein about 4.5 g of the mixed salt oxybate is administered per day.

41. The method of claim 40, wherein about 2.25 g of the mixed salt oxybate is administered twice per day.

42. The method of any one of claims 28-39, wherein about 6 g of the mixed salt oxybate is administered per day.

43. The method of claim 42, wherein about 3.0 g of the mixed salt oxybate is administered twice per day.

44. The method of any one of claims 28-39, wherein about 7.5 g of the mixed salt oxybate is administered per day.

45. The method of claim 44, wherein about 3.75 g of the mixed salt oxybate is administered twice per day.

46. The method of any one of claims 28-39, wherein about 9.0 g of the mixed salt oxybate is administered per day.

47. The method of claim 46, wherein about 4.5 g of the mixed salt oxybate is administered twice per day.

48. The method of any one of claims 28-47, wherein the mixed salt oxybate composition is a liquid.

49. The method of claim 48, wherein the concentration of the mixed salt oxybate in the liquid is from 350 mg/ml-650 mg/ml, or about 450 mg/ml-550 mg/ml.

50. The method of claim 48, wherein the concentration of the mixed salt oxybate in the liquid is about 0.5 g/mL.

51. The method of any one of claims 28-50, wherein the patient is treated for cataplexy.

52. The method of any one of claims 28-50, wherein the patient is treated for excessive daytime sleepiness in patients with narcolepsy.

53. The method of any one of claims 28-52, wherein the mixed salt oxybate is administered at bedtime.

54. The method of any one of claims 28-53, wherein the mixed salt oxybate is administered at bedtime and about 2.5 h-4 h after the bedtime administration.

55. A method for substituting a mixed salt oxybate composition for a sodium oxybate composition in a patient treated for cataplexy or excessive daytime sleepiness in patients with narcolepsy, the method comprising:

    a. Determining whether a patient treated with a therapeutically effective amount of sodium oxybate is sensitive to high sodium intake; and

    b. If the patient is sensitive to high sodium intake, then administering a therapeutically effective amount of a mixed salt oxybate to the patient,

    wherein the amount of the sodium oxybate and mixed salt oxybate are the same on an oxybate dosing strength basis.

56. The method of claim 55, wherein the mixed salt oxybate comprises sodium oxybate, potassium oxybate, magnesium oxybate and calcium oxybate, and wherein the mixed salt oxybate comprises about 5%-40% sodium oxybate (wt/wt%).

57. The method of claim 56, wherein the mixed salt oxybate comprises about 5%-40% of sodium oxybate (wt/wt%), about 10%-40% of potassium oxybate (wt/wt%), about 5%-30% of magnesium oxybate (wt/wt%), and about 20%-80% of calcium oxybate (wt/wt%).

58. The method of claim 57, wherein the mixed salt oxybate comprises about 8% mol. equiv. of sodium oxybate, about 23% mol. equiv. of potassium oxybate, about 21% mol. equiv. of magnesium oxybate and about 48% mol. equiv. of calcium oxybate.

59. The method of any one of claims 55-58, wherein the patient is in heart failure.

60. The method of any one of claims 55-58, wherein the patient is hypertensive.

61. The method of any one of claims 55-58, wherein the patient has renal impairment.

62. The method of any one of claims 55-58, wherein the patient is at risk for stroke.

63. The method of any one of claims 55-62, wherein about 2.0 g-10.0 g; about 3.0 g-9.5 g; or about 4.5 g-9.0 g of the mixed salt oxybate is administered per day.

64. The method of claim 63, wherein the mixed salt oxybate is administered twice per day.

65. The method of claim 63, wherein the mixed salt oxybate is administered once per day.

66. The method of any one of claims 55-65, wherein about 4.5 g of the mixed salt oxybate is administered per day.

67. The method of claim 66, wherein about 2.25 g of the mixed salt oxybate is administered twice per day.

68. The method of any one of claims 55-65, wherein about 6.0 g of the mixed salt oxybate is administered per day.

69. The method of claim 68, wherein about 3 g of the mixed salt oxybate is administered twice per day.

70. The method of any one of claims 55-65, wherein about 7.5 g of the mixed salt oxybate is administered per day.

71. The method of claim 70, wherein about 3.75 g of the mixed salt oxybate is administered twice per day.

72. The method of any one of claims 55-65, wherein about 9.0 g of the mixed salt oxybate is administered per day.

73. The method of claim 72, wherein about 4.5 g of the mixed salt oxybate is administered twice per day.

74. The method of any one of claims 55-73, wherein the mixed salt oxybate composition is a liquid.

75. The method of claim 74, wherein the concentration of the mixed salt oxybate in the liquid is from 350 mg/ml-650 mg/ml, or about 450 mg/ml-550 mg/ml.

76. The method of claim 74, wherein the concentration of the mixed salt oxybate in the liquid is about 0.5 g/mL.

77. The method of any one of claims 55-75 wherein the patient is treated for cataplexy.

78. The method of any one of claims 55-75, wherein the patient is treated for excessive daytime sleepiness in patients with narcolepsy.

79. The method of any one of claims 55-78, wherein the mixed salt oxybate is administered at bedtime.

80. The method of any one of claims 55-79, wherein the mixed salt oxybate is administered at bedtime and about 2.5 h-4 h after the bedtime administration.

81. The method of any one of claims 1-27, wherein the amount of the sodium oxybate and the mixed salt oxybate are the same on a gram for gram basis.

82. The method of any one of claims 28-54, wherein the switching comprises administering a therapeutically effective amount of the mixed salt oxybate to the patient and wherein the amount of sodium oxybate and mixed salt oxybate are the same on a gram for gram basis.