WHAT IS CLAIMED IS:

1. A dual release oral dosage system comprising (a) one or more of (i) doxylamine, (ii) an analog thereof, (iii) a derivative thereof, (iv) a prodrug thereof, (v) a metabolite thereof and (vi) a salt of any of (i)-(v); and (b) one or more of (i) pyridoxine, (ii) an analog thereof, (iii) a derivative thereof, (iv) a prodrug thereof, (v) a metabolite thereof and (vi) a salt of any of (i)-(v), said dual release oral dosage system comprising:

(A) an immediate release component comprising:

(a) one or more of (i) doxylamine, (ii) an analog thereof, (iii) a derivative thereof, (iv) a prodrug thereof, (v) a metabolite thereof and (vi) a salt of any of (i)-(v); and/or

(b) one or more of (i) pyridoxine, (ii) an analog thereof, (iii) a derivative thereof, (iv) a prodrug thereof, (v) a metabolite thereof and (vi) a salt of any of (i)-(v); and

(B) a delayed release component comprising:

(a) one or more of (i) doxylamine, (ii) an analog thereof, (iii) a derivative thereof, (iv) a prodrug thereof, (v) a metabolite thereof and/or (vi) a salt of any of (i)-(v); and/or

(b) one or more of (i) pyridoxine, (ii) an analog thereof, (iii) a derivative thereof, (iv) a prodrug thereof, (v) a metabolite thereof and (vi) a salt of any of (i)-(v);

wherein said immediate release component is for effecting release of (a) one or more of (i) doxylamine, (ii) an analog thereof, (iii) a derivative thereof, (iv) a prodrug thereof, (v) a metabolite thereof and/or (vi) a salt of any of (i)-(v), and/or (b) (i) one or more of (i) pyridoxine, (ii) an analog thereof, (iii) a derivative thereof, (iv) a prodrug thereof, (v) a metabolite thereof and (vi) a salt of any of (i)-(v), which begins prior to release of (a) one or more of (i) doxylamine, (ii) an analog thereof, (iii) a derivative thereof, (iv) a prodrug thereof, (v) a metabolite thereof and/or (vi) a salt of any of (i)-(v), and/or (b) (i) one or more of (i) pyridoxine, (ii) an analog thereof, (iii) a derivative thereof, (iv) a prodrug thereof, (v) a metabolite thereof and (vi) a salt of any of (i)-(v), from the delayed release component, within the gastrointestinal tract.

2. The dual release oral dosage system of claim 1, wherein said immediate release component is for effecting release substantially within the stomach.

3. The dual release oral dosage system of claim 1, wherein said delayed release component is for effecting release substantially within the intestine and there is substantially no release from said delayed release component in the stomach.

4. The dual release oral dosage system of any one of claims 1 to 3, wherein said system provides a maximum daily dosage of (i) doxylamine (ii) an analog thereof, (iii) a derivative thereof, (iv) a prodrug thereof, (v) a metabolite thereof and/or (vi) a salt of any of (i)-(v); of about 60 mg.

5. The dual release oral dosage system of claim 4, wherein said system provides a daily dosage of (i) doxylamine (ii) an analog thereof, (iii) a derivative thereof, (iv) a prodrug thereof, (v) a metabolite thereof and/or (vi) a salt of any of (i)-(v); of about 20 mg to about 60 mg.

6. The dual release oral dosage system of any one of claims 1 to 5, wherein said system provides an average C_{max} of doxylamine (ii) an analog thereof, (iii) a derivative thereof, (iv) a prodrug thereof, (v) a metabolite thereof and/or (vi) a salt of any of (i)-(v); up to about 250 ng/ml.

7. The dual release oral dosage system of claim 6, wherein said system provides an average C_{max} of doxylamine (ii) an analog thereof, (iii) a derivative thereof, (iv) a prodrug thereof, (v) a metabolite thereof and/or (vi) a salt of any of (i)-(v); of about 70 ng/ml to about 250 ng/ml.

8. The dual release oral dosage system of any one of claims 1 to 7, wherein said system provides a maximum daily dosage of (i) pyridoxine (ii) an analog thereof, (iii) a derivative thereof, (iv) a prodrug thereof, (v) a metabolite thereof and/or (vi) a salt of any of (i)-(v);), of about 100 mg.

9. The dual release oral dosage system of claim 8, wherein said system provides a daily dosage of (i) pyridoxine and(ii) an analog thereof, (iii) a derivative thereof, (iv) a prodrug thereof, (v) a metabolite thereof and/or (vi) a salt of any of (i)-(v); of about 1 mg to about 100 mg.

10. The dual release oral dosage system of any one of claims 1 to 9, wherein said system provides an average C_{max} of (i) pyridoxine and/or a pharmaceutically acceptable salt

thereof, (ii) a metabolite of pyridoxine and/or a pharmaceutically acceptable salt of said metabolite, or (iii) both (i) and (ii), of up to about 300 ng/ml.

11. The dual release oral dosage system of claim 10, wherein said system provides an average C_{max} of (i) pyridoxine (ii) an analog thereof, (iii) a derivative thereof, (iv) a prodrug thereof, (v) a metabolite thereof and/or (vi) a salt of any of (i)-(v); of about 10 ng/ml to about 300 ng/ml.

12. The dual release oral dosage system of any one of claims 1 to 11, wherein said system comprises at least two dual release oral dosage forms, wherein each of said oral dosage forms comprises:

(A) an immediate release composition comprising:

(a) one or more of (i) doxylamine, (ii) an analog thereof, (iii) a derivative thereof, (iv) a prodrug thereof, (v) a metabolite thereof and (vi) a salt of any of (i)-(v); and/or

(b) one or more of (i) pyridoxine, (ii) an analog thereof, (iii) a derivative thereof, (iv) a prodrug thereof, (v) a metabolite thereof and (vi) a salt of any of (i)-(v); and

(B) a delayed release composition comprising:

(a) one or more of (i) doxylamine, (ii) an analog thereof, (iii) a derivative thereof, (iv) a prodrug thereof, (v) a metabolite thereof and/or (vi) a salt of any of (i)-(v); and/or

(b) one or more of (i) pyridoxine, (ii) an analog thereof, (iii) a derivative thereof, (iv) a prodrug thereof, (v) a metabolite thereof and (vi) a salt of any of (i)-(v);

13. The dual release oral dosage system of claim 12, wherein said system consists of two to four of said dual release oral dosage forms.

14. The dual release oral dosage system of claim 12 or 13, wherein said system consists of two of said dual release oral dosage forms.

15. The dual release oral dosage system of any one of claims 12 to 14, wherein at least two of said dual release oral dosage forms are the same.

16. The dual release oral dosage system of claim 12 or 13, wherein all of said dual release oral dosage forms are the same.

17. The dual release oral dosage system of any one of claims 12 to 14, wherein at least two of said dual release oral dosage forms are different.

18. The dual release oral dosage system of claim 12 or 13, wherein all of said dual release oral dosage forms are different.

19. The dual release oral dosage system of claim 17 or 18, wherein each of said different dual release oral dosage forms comprises an identifying characteristic such that said different dual release oral dosage forms can be distinguished from one another.

20. The dual release oral dosage system of claim 19, where said identifying characteristic is shape, color, an identifying mark, or any combination thereof.

21. The dual release oral dosage system of any one of claims 12 to 20, wherein said immediate release composition and said delayed release composition are comprised in said dual release oral dosage form in a layered arrangement with respect to one another.

22. The dual release oral dosage system of any one of claims 12 to 20, wherein said immediate release composition and said delayed release composition are comprised in said dual release oral dosage form adjacent to one another.

23. The dual release oral dosage system of any one of claims 12 to 20, wherein said dual release oral dosage form comprises (a) a core comprising said delayed release composition and (b) one or more coats substantially surrounding said core, said one or more coats comprising said immediate release composition.

24. The dual release oral dosage system of any one of claims 12 to 20, wherein said dual release oral dosage form comprises (a) delayed release granules or microspheres comprising said delayed release composition and (b) immediate release granules or microspheres comprising said immediate release composition.

25. The dual release oral dosage system of any one of claims 12 to 24, wherein said immediate release composition is in contact with said delayed release composition, within said dual release oral dosage form.

26. The dual release oral dosage system of any one of claims 12 to 24, wherein said immediate release composition is not in contact with said delayed release composition, within said dual release oral dosage form.

27. The dual release oral dosage system of any one of claims 12 to 26, wherein said immediate release composition, delayed release composition, or both, further comprise at least one pharmaceutically acceptable carrier or excipient.

28. The dual release oral dosage system of any one of claims 1 to 27, where said immediate release component or composition comprises (a) doxylamine and/or a pharmaceutically acceptable salt thereof; and/or (b) (i) pyridoxine (ii) an analog thereof, (iii) a derivative thereof, (iv) a prodrug thereof, (v) a metabolite thereof and/or (vi) a salt of any of (i)-(v).

29. The dual release oral dosage system of any one of claims 1 to 28, wherein said metabolite is pyridoxal, pyridoxal-5-phosphate, pyridoxamine, pyridoxamine-5-phosphate or pyridoxine phosphate.

30. The dual release oral dosage system of any one of claims 1 to 27, where said immediate release component or composition comprises (a) doxylamine and/or a pharmaceutically acceptable salt thereof; and/or (b) (i) pyridoxine (ii) an analog thereof, (iii) a derivative thereof, (iv) a prodrug thereof, (v) a metabolite or two or more metabolites thereof ,and/or (vi) a salt of any of (i)-(v).

31. The dual release oral dosage system of claim 30, wherein said two or more metabolites are any combination of two or more of pyridoxal, pyridoxal-5-phosphate, pyridoxamine, pyridoxamine-5-phosphate and pyridoxine phosphate.

32. The dual release oral dosage system of any one of claims 1 to 27, where said delayed release component or composition comprises (a) doxylamine and/or a pharmaceutically acceptable salt thereof; and/or (b) (i) pyridoxine (ii) an analog thereof, (iii) a derivative thereof, (iv) a prodrug thereof, (v) a metabolite thereof and/or (vi) a salt of any of (i)-(v);

33. The dual release oral dosage system of any one of claims 1 to 27, where said delayed release component or composition comprises (a) doxylamine and/or a pharmaceutically acceptable salt thereof; and/or (b) (i) pyridoxine, (ii) an analog thereof, (iii) a derivative thereof, (iv) a prodrug thereof, (v) a metabolite or two or more metabolites thereof and (vi) a salt of any of (i)-(v).

34. The dual release oral dosage system of claim 33, wherein said two or more metabolites are any combination of two or more of pyridoxal, pyridoxal-5-phosphate, pyridoxamine, pyridoxamine-5-phosphate and pyridoxine phosphate.

35. The dual release oral dosage system of any one of claims 12 to 34, where said dual release oral dosage form is a tablet, pill, capsule, solution or flowable powder.

36. A dual release oral dosage form comprising (a) one or more of (i) doxylamine, (ii) an analog thereof, (iii) a derivative thereof, (iv) a prodrug thereof, (v) a metabolite thereof and (vi) a salt of any of (i)-(v); and (b) one or more of (i) pyridoxine, (ii) an analog thereof, (iii) a derivative thereof, (iv) a prodrug thereof, (v) a metabolite thereof and (vi) a salt of any of (i)-(v), said dual release oral dosage form comprising:

(A) an immediate release composition comprising:

(a) one or more of (i) doxylamine, (ii) an analog thereof, (iii) a derivative thereof, (iv) a prodrug thereof, (v) a metabolite thereof and (vi) a salt of any of (i)-(v); and/or

(b) one or more of (i) pyridoxine, (ii) an analog thereof, (iii) a derivative thereof, (iv) a prodrug thereof, (v) a metabolite thereof and (vi) a salt of any of (i)-(v); and

(B) a delayed release composition comprising:

(a) one or more of (i) doxylamine, (ii) an analog thereof, (iii) a derivative thereof, (iv) a prodrug thereof, (v) a metabolite thereof and (vi) a salt of any of (i)-(v); and/or

(b) one or more of (i) pyridoxine, (ii) an analog thereof, (iii) a derivative thereof, (iv) a prodrug thereof, (v) a metabolite thereof and (vi) a salt of any of (i)-(v);

wherein said immediate release composition is for effecting release of (a) one or more of (i) doxylamine, (ii) an analog thereof, (iii) a derivative thereof, (iv) a prodrug thereof, (v) a metabolite thereof and/or (vi) a salt of any of (i)-(v), and/or (b) (i) one or more of (i) pyridoxine, (ii) an analog thereof, (iii) a derivative thereof, (iv) a prodrug thereof, (v) a metabolite thereof and (vi) a salt of any of (i)-(v), which begins prior to release of (a) one or more of (i) doxylamine, (ii) an analog thereof, (iii) a derivative thereof, (iv) a prodrug thereof, (v) a metabolite thereof and/or (vi) a salt of any of (i)-(v), and/or (b) (i) one or more of (i) pyridoxine, (ii) an analog thereof, (iii) a derivative thereof, (iv) a prodrug thereof, (v) a metabolite thereof and (vi) a salt of any of (i)-(v), from the delayed release component, within the gastrointestinal tract.

37. The dual release oral dosage form of claim 36, wherein said immediate release composition is for effecting release substantially within the stomach.

38. The dual release oral dosage form of claim 36 or 37, wherein said delayed release composition is for effecting release substantially within the intestine, and there is substantially no release from said delayed release composition in the stomach.

39. The dual release oral dosage form of any one of claims 36 to 38, wherein said dosage form comprises about 40 mg or less of (i) doxylamine (ii) an analog thereof, (iii) a derivative thereof, (iv) a prodrug thereof, (v) a metabolite thereof and/or (vi) a salt of any of (i)-(v).

40. The dual release oral dosage form of claim 39, wherein said dosage form comprises about 30 mg or less of (i) doxylamine (ii) an analog thereof, (iii) a derivative thereof, (iv) a prodrug thereof, (v) a metabolite thereof and/or (vi) a salt of any of (i)-(v).

41. The dual release oral dosage form of claim 40, wherein said dosage form comprises about 20 mg or less of (i) doxylamine (ii) an analog thereof, (iii) a derivative thereof, (iv) a prodrug thereof, (v) a metabolite thereof and/or (vi) a salt of any of (i)-(v).

42. The dual release oral dosage form of claim 41, wherein said dosage form comprises about 10 mg or less of (i) doxylamine (ii) an analog thereof, (iii) a derivative thereof, (iv) a prodrug thereof, (v) a metabolite thereof and/or (vi) a salt of any of (i)-(v).

43. The dual release oral dosage form of any one of claims 36 to 42, wherein said dosage form comprises at least about 5 mg of (i) doxylamine (ii) an analog thereof, (iii) a derivative thereof, (iv) a prodrug thereof, (v) a metabolite thereof and/or (vi) a salt of any of (i)-(v).

44. The dual release oral dosage form of any one of claims 36 to 39, wherein said dosage form comprises from about 5 mg to about 40 mg of (i) doxylamine (ii) an analog thereof, (iii) a derivative thereof, (iv) a prodrug thereof, (v) a metabolite thereof and/or (vi) a salt of any of (i)-(v).

45. The dual release oral dosage form of claim 44, wherein said dosage form comprises from about 5 mg to about 30 mg of (i) doxylamine (ii) an analog thereof, (iii) a derivative thereof, (iv) a prodrug thereof, (v) a metabolite thereof and/or (vi) a salt of any of (i)-(v).

46. The dual release oral dosage form of claim 45, wherein said dosage form comprises from about 5 mg to about 20 mg of (i) doxylamine (ii) an analog thereof, (iii) a derivative thereof, (iv) a prodrug thereof, (v) a metabolite thereof and/or (vi) a salt of any of (i)-(v).

47. The dual release oral dosage form of claim 46, wherein said dosage form comprises from about 5 mg to about 10 mg of (i) doxylamine (ii) an analog thereof, (iii) a derivative thereof, (iv) a prodrug thereof, (v) a metabolite thereof and/or (vi) a salt of any of (i)-(v).

48. The dual release oral dosage form of claim 46, wherein said dosage form comprises from about 10 mg to about 20 mg of (i) doxylamine (ii) an analog thereof, (iii) a derivative thereof, (iv) a prodrug thereof, (v) a metabolite thereof and/or (vi) a salt of any of (i)-(v).

49. The dual release oral dosage form of claim 48, wherein said dosage form comprises about 20 mg of (i) doxylamine (ii) an analog thereof, (iii) a derivative thereof, (iv) a prodrug thereof, (v) a metabolite thereof and/or (vi) a salt of any of (i)-(v).

50. The dual release oral dosage form of any one of claims 36 to 49, wherein said dosage form comprises about 80 mg or less of (i) pyridoxine (ii) an analog thereof, (iii) a derivative thereof, (iv) a prodrug thereof, (v) a metabolite thereof and/or (vi) a salt of any of (i)-(v).

51. The dual release oral dosage form of claim 50, wherein said dosage form comprises about 50 mg or less of (i) pyridoxine (ii) an analog thereof, (iii) a derivative thereof, (iv) a prodrug thereof, (v) a metabolite thereof and/or (vi) a salt of any of (i)-(v).

52. The dual release oral dosage form of claim 51, wherein said dosage form comprises about 25 mg or less of (i) pyridoxine (ii) an analog thereof, (iii) a derivative thereof, (iv) a prodrug thereof, (v) a metabolite thereof and/or (vi) a salt of any of (i)-(v).

53. The dual release oral dosage form of claim 52, wherein said dosage form comprises about 20 mg or less of (i) pyridoxine (ii) an analog thereof, (iii) a derivative thereof, (iv) a prodrug thereof, (v) a metabolite thereof and/or (vi) a salt of any of (i)-(v).

54. The dual release oral dosage form of claim 53, wherein said dosage form comprises about 10 mg or less of (i) pyridoxine (ii) an analog thereof, (iii) a derivative thereof, (iv) a prodrug thereof, (v) a metabolite thereof and/or (vi) a salt of any of (i)-(v).

55. The dual release oral dosage form of any one of claims 36 to 54, wherein said dosage form comprises at least about 5 mg of (i) pyridoxine (ii) an analog thereof, (iii) a derivative thereof, (iv) a prodrug thereof, (v) a metabolite thereof and/or (vi) a salt of any of (i)-(v).

56. The dual release oral dosage form of any one of claims 36 to 50, wherein said dosage form comprises from about 5 mg to about 80 mg of (i) pyridoxine (ii) an analog thereof, (iii) a derivative thereof, (iv) a prodrug thereof, (v) a metabolite thereof and/or (vi) a salt of any of (i)-(v).

57. The dual release oral dosage form of claim 56, wherein said dosage form comprises from about 5 mg to about 50 mg of (i) pyridoxine (ii) an analog thereof, (iii) a derivative thereof, (iv) a prodrug thereof, (v) a metabolite thereof and/or (vi) a salt of any of (i)-(v).

58. The dual release oral dosage form of claim 57, wherein said dosage form comprises from about 5 mg to about 25 mg of (i) pyridoxine (ii) an analog thereof, (iii) a derivative thereof, (iv) a prodrug thereof, (v) a metabolite thereof and/or (vi) a salt of any of (i)-(v).

59. The dual release oral dosage form of claim 58, wherein said dosage form comprises from about 10 mg to about 25 mg of (i) pyridoxine (ii) an analog thereof, (iii) a derivative thereof, (iv) a prodrug thereof, (v) a metabolite thereof and/or (vi) a salt of any of (i)-(v).

60. The dual release oral dosage form of claim 59, wherein said dosage form comprises from about 10 mg to about 20 mg of (i) pyridoxine (ii) an analog thereof, (iii) a derivative thereof, (iv) a prodrug thereof, (v) a metabolite thereof and/or (vi) a salt of any of (i)-(v).

61. The dual release oral dosage form of claim 60, wherein said dosage form comprises about 20 mg of (i) pyridoxine (ii) an analog thereof, (iii) a derivative thereof, (iv) a prodrug thereof, (v) a metabolite thereof and/or (vi) a salt of any of (i)-(v).

62. The dual release oral dosage form of any one of claims 36 to 61, wherein said dosage form comprises an identifying characteristic for correlation with its administration in a dosage regimen.

63. The dual release oral dosage form of claim 62, where said identifying characteristic is shape, color, an identifying mark, or any combination thereof.

64. The dual release oral dosage form of any one of claims 36 to 63, wherein said immediate release composition and said delayed release composition are comprised in said dual release oral dosage form in a layered arrangement with respect to one another.

65. The dual release oral dosage form of any one of claims 36 to 63, wherein said immediate release composition and said delayed release composition are comprised in said dual release oral dosage form adjacent to one another.

66. The dual release oral dosage form of any one of claims 36 to 63, wherein said dual release oral dosage form comprises (a) a core comprising said delayed release composition and (b) one or more coats substantially surrounding said core, said one or more coats comprising said immediate release composition.

67. The dual release oral dosage form of any one of claims 36 to 63, wherein said dual release oral dosage form comprises (a) delayed release granules or microspheres comprising said delayed release composition and (b) immediate release granules or microspheres comprising said immediate release composition.

68. The dual release oral dosage form of any one of claims 36 to 67, wherein said immediate release composition is in contact with said delayed release composition, within said dual release oral dosage form.

69. The dual release oral dosage form of any one of claims 36 to 67, wherein said immediate release composition is not in contact with said delayed release composition, within said dual release oral dosage form.

70. The dual release oral dosage form of any one of claims 36 to 69, wherein said immediate release composition, delayed release composition, or both, further comprise at least one pharmaceutically acceptable carrier or excipient.

71. The dual release oral dosage form of any one of claims 36 to 70, where said immediate release composition comprises (a) (i) doxylamine (ii) an analog thereof, (iii) a derivative thereof, (iv) a prodrug thereof, (v) a metabolite thereof and/or (vi) a salt of any of (i)-(v); and/or (b) (i) pyridoxine (ii) an analog thereof, (iii) a derivative thereof, (iv) a prodrug thereof, (v) a metabolite thereof and/or (vi) a salt of any of (i)-(v).

72. The dual release oral dosage form of any one of claims 36 to 71, wherein said metabolite is pyridoxal, pyridoxal-5-phosphate, pyridoxamine, pyridoxamine-5-phosphate or pyridoxine phosphate.

73. The dual release oral dosage form of any one of claims 36 to 70, where said immediate release composition comprises (a) (i) doxylamine (ii) an analog thereof, (iii) a derivative thereof, (iv) a prodrug thereof, (v) a metabolite thereof and/or (vi) a salt of any of (i)-(v); and/or (b) (i) pyridoxine (ii) two or more metabolites of pyridoxine or (iii) an analog thereof, (iv) a derivative thereof, (v) a prodrug thereof, (vi) a metabolite thereof and/or (vii) a salt of any of (i)-(vi).

74. The dual release oral dosage form of claim 73, wherein said two or more metabolites are any combination of two or more of pyridoxal, pyridoxal-5-phosphate, pyridoxamine, pyridoxamine-5-phosphate and pyridoxine phosphate.

75. The dual release oral dosage form of any one of claims 36 to 70, wherein said delayed release composition comprises (a) doxylamine and/or a pharmaceutically acceptable salt thereof; and/or (b) (i) pyridoxine (ii) an analog thereof, (iii) a derivative thereof, (iv) a prodrug thereof, (v) a metabolite thereof and/or (vi) a salt of any of (i)-(v).

76. The dual release oral dosage form of claim 75, wherein said metabolite is pyridoxal, pyridoxal-5-phosphate, pyridoxamine, pyridoxamine-5-phosphate or pyridoxine phosphate.

77. The dual release oral dosage form of any one of claims 36 to 70, where said delayed release composition comprises (a) doxylamine and/or a pharmaceutically acceptable salt thereof; and/or (b) (i) pyridoxine, (ii) an analog thereof, (iii) a derivative thereof, (iv) a prodrug thereof, (v) a metabolite or two or more metabolites thereof and/or (vi) a salt of any of (i)-(v).

78. The dual release oral dosage form of claim 77, wherein said two or more metabolites are any combination of two or more of pyridoxal, pyridoxal-5-phosphate, pyridoxamine, pyridoxamine-5-phosphate and pyridoxine phosphate.

79. The dual release oral dosage form of any one of claims 36 to 78, where said dual release oral dosage form is a tablet, pill, capsule, solution or flowable powder.

80. The dual release oral dosage system of any one of claims 1 to 35 or the dual release oral dosage form of any one of claims 36 to 79 wherein the amount of (i) doxylamine, (ii) an analog thereof, (iii) a derivative thereof, (iv) a prodrug thereof, (v) a metabolite thereof and/or (vi) a salt of any of (i)-(v); comprised in the immediate release component or composition is less than the amount of doxylamine (ii) an analog thereof, (iii) a derivative thereof, (iv) a prodrug thereof, (v) a metabolite thereof and/or (vi) a salt of any of (i)-(v); comprised in the delayed release component or composition.

81. The dual release oral dosage system of any one of claims 1 to 35 or the dual release oral dosage form of any one of claims 36 to 79, wherein the amount of (i) doxylamine (ii) an analog thereof, (iii) a derivative thereof, (iv) a prodrug thereof, (v) a metabolite thereof and/or (vi) a salt of any of (i)-(v); comprised in the immediate release component or composition is more than the amount of (i) doxylamine (ii) an analog thereof, (iii) a derivative thereof, (iv) a prodrug thereof, (v) a metabolite thereof and/or (vi) a salt of any of (i)-(v); comprised in the delayed release component or composition.

82. The dual release oral dosage system of any one of claims 1 to 35 or the dual release oral dosage form of any one of claims 36 to 79, wherein the amount of (i) doxylamine (ii) an analog thereof, (iii) a derivative thereof, (iv) a prodrug thereof, (v) a metabolite thereof and/or (vi) a salt of any of (i)-(v); comprised in the immediate release component or composition is substantially equivalent to the amount of doxylamine (ii) an analog thereof, (iii) a derivative thereof, (iv) a prodrug thereof, (v) a metabolite thereof and/or (vi) a salt of any of (i)-(v); comprised in the delayed release component or composition.

83. The dual release oral dosage system of any one of claims 1 to 35 or the dual release oral dosage form of any one of claims 36 to 79, wherein the amount of (i) pyridoxine (ii) an analog thereof, (iii) a derivative thereof, (iv) a prodrug thereof, (v) a metabolite thereof and/or (vi) a salt of any of (i)-(v); comprised in the immediate release component or composition is less than the amount of (i) pyridoxine (ii) an analog thereof, (iii) a derivative thereof, (iv) a prodrug thereof, (v) a metabolite thereof and/or (vi) a salt of any of (i)-(v); comprised in the delayed release component or composition.

84. The dual release oral dosage system of any one of claims 1 to 35 or the dual release oral dosage form of any one of claims 36 to 79, wherein the amount of (i) pyridoxine (ii) an analog thereof, (iii) a derivative thereof, (iv) a prodrug thereof, (v) a metabolite thereof and/or (vi) a salt of any of (i)-(v); comprised in the immediate release component or

composition is more than the amount of (i) pyridoxine (ii) an analog thereof, (iii) a derivative thereof, (iv) a prodrug thereof, (v) a metabolite thereof and/or (vi) a salt of any of (i)-(v); comprised in the delayed release component or composition.

85. The dual release oral dosage system of any one of claims 1 to 35 or the dual release oral dosage form of any one of claims 36 to 79, wherein the amount of (i) pyridoxine (ii) an analog thereof, (iii) a derivative thereof, (iv) a prodrug thereof, (v) a metabolite thereof and/or (vi) a salt of any of (i)-(v); comprised in the immediate release component or composition is substantially equivalent to the amount of (i) pyridoxine (ii) an analog thereof, (iii) a derivative thereof, (iv) a prodrug thereof, (v) a metabolite thereof and/or (vi) a salt of any of (i)-(v); comprised in the delayed release component or composition.

86. The dual release oral dosage system of any one of claims 1 to 35 and 80 to 85, or the dual release oral dosage form of any one of claims 36 to 85, wherein the ratio, by weight, of the amount of (i) doxylamine, (ii) an analog thereof, (iii) a derivative thereof, (iv) a prodrug thereof, (v) a metabolite thereof and/or (vi) a salt of any of (i)-(v); in the immediate release component or composition to the amount of (i) doxylamine, (ii) an analog thereof, (iii) a derivative thereof, (iv) a prodrug thereof, (v) a metabolite thereof and/or (vi) a salt of any of (i)-(v); comprised in the delayed release component or composition is from about 5:1 to about 1:5.

87. The dual release oral dosage system of any one of claims 1 to 35 and 80 to 85, or the dual release oral dosage form of any one of claims 36 to 85, wherein the ratio, by weight, of the amount of (i) doxylamine, (ii) an analog thereof, (iii) a derivative thereof, (iv) a prodrug thereof, (v) a metabolite thereof and/or (vi) a salt of any of (i)-(v); comprised in the immediate release component or composition to the amount of (i) doxylamine, (ii) an analog thereof, (iii) a derivative thereof, (iv) a prodrug thereof, (v) a metabolite thereof and/or (vi) a salt of any of (i)-(v); comprised in the delayed release component or composition is from about 4:1 to about 1:4.

88. The dual release oral dosage system of any one of claims 1 to 35 and 80 to 85, or the dual release oral dosage form of any one of claims 36 to 85, wherein the ratio, by weight, of the amount of (i) doxylamine, (ii) an analog thereof, (iii) a derivative thereof, (iv) a prodrug thereof, (v) a metabolite thereof and/or (vi) a salt of any of (i)-(v); comprised in the immediate release component or composition to the amount of (i) doxylamine, (ii) an analog thereof, (iii) a derivative thereof, (iv) a prodrug thereof, (v) a

metabolite thereof and/or (vi) a salt of any of (i)-(v); comprised in the delayed release component or composition is from about 3:1 to about 1:3.

89. The dual release oral dosage system of any one of claims 1 to 35 and 80 to 85, or the dual release oral dosage form of any one of claims 36 to 85, wherein the ratio, by weight, of the amount of (i) doxylamine, (ii) an analog thereof, (iii) a derivative thereof, (iv) a prodrug thereof, (v) a metabolite thereof and/or (vi) a salt of any of (i)-(v); comprised in the immediate release component or composition to the amount of doxylamine (ii) an analog thereof, (iii) a derivative thereof, (iv) a prodrug thereof, (v) a metabolite thereof and/or (vi) a salt of any of (i)-(v); comprised in the delayed release component or composition is from about 2:1 to about 1:2.

90. The dual release oral dosage system of any one of claims 1 to 35 and 80 to 85, or the dual release oral dosage form of any one of claims 36 to 85, wherein the ratio, by weight, of the amount of (i) pyridoxine, (ii) an analog thereof, (iii) a derivative thereof, (iv) a prodrug thereof, (v) a metabolite thereof and/or (vi) a salt of any of (i)-(v); comprised in the immediate release component or composition to the amount of (i) pyridoxine, (ii) an analog thereof, (iii) a derivative thereof, (iv) a prodrug thereof, (v) a metabolite thereof and/or (vi) a salt of any of (i)-(v); comprised in the delayed release component or composition, is from about 5:1 to about 1:5.

91. The dual release oral dosage system of any one of claims 1 to 35 and 80 to 85, or the dual release oral dosage form of any one of claims 36 to 85 wherein the ratio, by weight, of the amount of (i) pyridoxine, (ii) an analog thereof, (iii) a derivative thereof, (iv) a prodrug thereof, (v) a metabolite thereof and/or (vi) a salt of any of (i)-(v); comprised in the immediate release component or composition to the amount of (i) pyridoxine, (ii) an analog thereof, (iii) a derivative thereof, (iv) a prodrug thereof, (v) a metabolite thereof and/or (vi) a salt of any of (i)-(v); comprised in the delayed release component or composition, is from about 4:1 to about 1:4.

92. The dual release oral dosage system of any one of claims 1 to 35 and 80 to 85, or the dual release oral dosage form of any one of claims 36 to 85, wherein the ratio, by weight, of the amount of (i) pyridoxine, (ii) an analog thereof, (iii) a derivative thereof, (iv) a prodrug thereof, (v) a metabolite thereof and/or (vi) a salt of any of (i)-(v); comprised in the immediate release component or composition to the amount of (i) pyridoxine, (ii) an analog thereof, (iii) a derivative thereof, (iv) a prodrug thereof, (v) a metabolite thereof

and/or (vi) a salt of any of (i)-(v); comprised in the delayed release component or composition, is from about 3:1 to about 1:3.

93. The dual release oral dosage system of any one of claims 1 to 35 and 80 to 85, or the dual release oral dosage form of any one of claims 36 to 85, wherein the ratio, by weight, of the amount of (i) pyridoxine, (ii) an analog thereof, (iii) a derivative thereof, (iv) a prodrug thereof, (v) a metabolite thereof and/or (vi) a salt of any of (i)-(v); comprised in the immediate release component or composition to the amount of (i) pyridoxine, (ii) an analog thereof, (iii) a derivative thereof, (iv) a prodrug thereof, (v) a metabolite thereof and/or (vi) a salt of any of (i)-(v); comprised in the delayed release component or composition, is from about 2:1 to about 1:2.

94. Use of the dual release oral dosage system of any one of claims 1 to 35 and 80 to 93, or the dual release oral dosage form of any one of claims 36 to 93, for alleviating the symptoms of nausea and vomiting in a mammal.

95. Use of the dual release oral dosage system of any one of claims 1 to 35 and 80 to 93, or the dual release oral dosage form of any one of claims 36 to 93, for the preparation of a medicament for alleviating the symptoms of nausea and vomiting in a mammal.

96. Use of the dual release oral dosage system of any one of claims 1 to 35 and 80 to 93, or the dual release oral dosage form of any one of claims 36 to 93, for alleviating the symptoms of nausea and vomiting of human pregnancy.

97. Use of the dual release oral dosage system of any one of claims 1 to 35 and 80 to 93, or the dual release oral dosage form of any one of claims 36 to 93, for the preparation of a medicament for alleviating the symptoms of nausea and vomiting of human pregnancy.

98. The use of any one of claims 94 to 97, wherein said dual release oral dosage system or dual release oral dosage form is for administration under fasted conditions.

99. The use of any one of claims 94 to 97, wherein said the dual release oral dosage system or dual release oral dosage form is for administration under fed conditions.

100. The dual release oral dosage system of any one of claims 1 to 35 and 80 to 93, or the dual release oral dosage form of any one of claims 36 to 93, for use in alleviating the symptoms of nausea and vomiting in a mammal.

101. The dual release oral dosage system of any one of claims 1 to 35 and 80 to 93, or the dual release oral dosage form of any one of claims 36 to 93, for use in the preparation of a medicament for alleviating the symptoms of nausea and vomiting in a mammal.

102. The dual release oral dosage system of any one of claims 1 to 35 and 80 to 93, or the dual release oral dosage form of any one of claims 36 to 93, for use in alleviating the symptoms of nausea and vomiting of human pregnancy.

103. The dual release oral dosage system of any one of claims 1 to 35 and 80 to 93, or the dual release oral dosage form of any one of claims 36 to 93, for use in the preparation of a medicament for alleviating the symptoms of nausea and vomiting of human pregnancy.

104. The dual release oral dosage system or dual release oral dosage form of any one of claims 100 to 103, for administration under fasted conditions.

105. The dual release oral dosage system or dual release oral dosage form of any one of claims 100 to 103, for administration under fed conditions.

106. A method for alleviating the symptoms of nausea and vomiting in a mammal, said method comprising administering the dual release oral dosage system of any one of claims 1 to 35 and 80 to 93, or the dual release oral dosage form of any one of claims 36 to 93, to a mammal in need thereof.

107. A method for alleviating the symptoms of nausea and vomiting during in human pregnancy, said method comprising administering dual release oral dosage system of any one of claims 1 to 35 and 80 to 93, or the dual release oral dosage form of any one of claims 36 to 93, to a pregnant human female in need thereof.

108. The method of claim 106 or 107, wherein said dual release oral dosage system or dual release oral dosage form is administered under fasted conditions.

109. The method of claim 106 or 107, wherein said dual release oral dosage system or dual release oral dosage form is administered under fed conditions.

110. A kit for use in alleviating the symptoms of nausea and vomiting in a mammal, said kit comprising the dual release oral dosage system of any one of claims 1 to 35 and 80 to 93, or the dual release oral dosage form of any one of claims 36 to 93.

111. The kit of claim 110, further comprising instructions for use of said dual release oral dosage system or said dual release oral dosage form for alleviating the symptoms of nausea and vomiting in a mammal.

112. A kit for use in alleviating the symptoms of nausea and vomiting of human pregnancy, said kit comprising the dual release oral dosage system of any one of claims 1 to 35 and 80 to 93, or the dual release oral dosage form of any one of claims 36 to 93.

113. The kit of claim 112, further comprising instructions for use of said dual release oral dosage system or said dual release oral dosage form for alleviating the symptoms of nausea and vomiting in human pregnancy.

114. The kit of any one of claims 110 to 113, further comprising instructions for administration of said dual release oral dosage system or said dual release oral dosage form under fasted conditions.

115. The kit of any one of claims 110 to 113, further comprising instructions for administration of said dual release oral dosage system or said dual release oral dosage form under fed conditions.

WHAT IS CLAIMED IS:

1. A dual release oral dosage form comprising:

(A) an immediate release composition comprising:

(a) from about 5 mg to about 20 mg of one or more of (i) doxylamine, (ii) an analog thereof, (iii) a derivative thereof, (iv) a prodrug thereof, (v) a metabolite thereof and (vi) a salt of any of (i)-(v); and/or

(b) from about 5 mg to about 20 mg of one or more of (i) pyridoxine, (ii) an analog thereof, (iii) a derivative thereof, (iv) a prodrug thereof, (v) a metabolite thereof and (vi) a salt of any of (i)-(v); and

(B) a delayed release composition comprising:

(a) from about 5 mg to about 20 mg of one or more of (i) doxylamine, (ii) an analog thereof, (iii) a derivative thereof, (iv) a prodrug thereof, (v) a metabolite thereof and (vi) a salt of any of (i)-(v); and

(b) from about 5 mg to about 20 mg of one or more of (i) pyridoxine, (ii) an analog thereof, (iii) a derivative thereof, (iv) a prodrug thereof, (v) a metabolite thereof and (vi) a salt of any of (i)-(v);

wherein said immediate release composition is for effecting release of (a) one or more of (i) doxylamine, (ii) an analog thereof, (iii) a derivative thereof, (iv) a prodrug thereof, (v) a metabolite thereof and/or (vi) a salt of any of (i)-(v), and/or (b) (i) one or more of (i) pyridoxine, (ii) an analog thereof, (iii) a derivative thereof, (iv) a prodrug thereof, (v) a metabolite thereof and (vi) a salt of any of (i)-(v), which begins prior to release of (a) one or more of (i) doxylamine, (ii) an analog thereof, (iii) a derivative thereof, (iv) a prodrug thereof, (v) a metabolite thereof and/or (vi) a salt of any of (i)-(v), and/or (b) (i) one or more of (i) pyridoxine, (ii) an analog thereof, (iii) a derivative thereof, (iv) a prodrug thereof, (v) a metabolite thereof and (vi) a salt of any of (i)-(v), from the delayed release component, within the gastrointestinal tract.

2. The dual release oral dosage form of claim 1, wherein said immediate release composition is for effecting release substantially within the stomach.

3. The dual release oral dosage form of claim 1 or 2, wherein said delayed release composition is for effecting release substantially within the intestine, and there is substantially no release from said delayed release composition in the stomach.

4. The dual release oral dosage form of any one of claims 1 to 3, wherein said dosage form comprises from about 10 mg to about 20 mg of (i) doxylamine (ii) an analog thereof, (iii) a derivative thereof, (iv) a prodrug thereof, (v) a metabolite thereof and/or (vi) a salt of any of (i)-(v).

5. The dual release oral dosage form of claim 4, wherein said dosage form comprises about 20 mg of (i) doxylamine (ii) an analog thereof, (iii) a derivative thereof, (iv) a prodrug thereof, (v) a metabolite thereof and/or (vi) a salt of any of (i)-(v).

6. The dual release oral dosage form of claim 5, wherein said dosage form comprises from about 10 mg to about 20 mg of (i) pyridoxine (ii) an analog thereof, (iii) a derivative thereof, (iv) a prodrug thereof, (v) a metabolite thereof and/or (vi) a salt of any of (i)-(v).

7. The dual release oral dosage form of claim 6, wherein said dosage form comprises about 20 mg of (i) pyridoxine (ii) an analog thereof, (iii) a derivative thereof, (iv) a prodrug thereof, (v) a metabolite thereof and/or (vi) a salt of any of (i)-(v).

8. The dual release oral dosage form of any one of claims 1 to 7, wherein said dosage form comprises an identifying characteristic for correlation with its administration in a dosage regimen.

9. The dual release oral dosage form of claim 8, where said identifying characteristic is shape, color, an identifying mark, or any combination thereof.

10. The dual release oral dosage form of any one of claims 1 to 9, wherein said dual release oral dosage form comprises (a) a core comprising said delayed release

composition and (b) one or more coats substantially surrounding said core, said one or more coats comprising said immediate release composition.

11. The dual release oral dosage form of claim 10, wherein said core is coated with an enteric material.

12. The dual release oral dosage form of any one of claims 1 to 11, wherein said immediate release composition is not in contact with said delayed release composition, within said dual release oral dosage form.

13. The dual release oral dosage form of any one of claims 1 to 12, wherein said immediate release composition, delayed release composition, or both, further comprise at least one pharmaceutically acceptable carrier or excipient.

14. The dual release oral dosage form of any one of claims 1 to 13, where said immediate release composition comprises a pharmaceutically acceptable doxylamine salt; and a pharmaceutically acceptable pyridoxine salt.

15. The dual release oral dosage form of any one of claims 1 to 14, wherein said delayed release composition comprises a pharmaceutically acceptable doxylamine salt; and a pharmaceutically acceptable pyridoxine salt.

16. The dual release oral dosage form of any one of claims 1 to 15, where said dual release oral dosage form is a tablet.

17. The dual release oral dosage form of any one of claims 1 to 16, wherein the amount of (i) doxylamine (ii) an analog thereof, (iii) a derivative thereof, (iv) a prodrug thereof, (v) a metabolite thereof and/or (vi) a salt of any of (i)-(v); comprised in the immediate release composition is substantially equivalent to the amount of doxylamine (ii) an analog thereof, (iii) a derivative thereof, (iv) a prodrug thereof, (v) a metabolite thereof and/or (vi) a salt of any of (i)-(v); comprised in the delayed release composition.

18. The dual release oral form of any one of claims 1 to 17, wherein the amount of (i) pyridoxine (ii) an analog thereof, (iii) a derivative thereof, (iv) a prodrug thereof, (v) a metabolite thereof and/or (vi) a salt of any of (i)-(v); comprised in the immediate release composition is substantially equivalent to the amount of (i) pyridoxine (ii) an analog thereof, (iii) a derivative thereof, (iv) a prodrug thereof, (v) a metabolite thereof and/or (vi) a salt of any of (i)-(v); comprised in the delayed release composition.

19. The dual release oral dosage form of any one of claims 1 to 18, wherein said pharmaceutically acceptable doxylamine salt is doxylamine succinate.

20. The dual release oral dosage form of any one of claims 1 to 19, wherein said pharmaceutically acceptable pyridoxine salt is pyridoxine hydrochloride.

21. The dual release oral dosage form of any one of claims 1 to 20, wherein said immediate release composition comprises about 10 mg of doxylamine succinate and about 10 mg of pyridoxine hydrochloride, and said delayed release composition comprises about 10 mg of doxylamine succinate and about 10 mg of pyridoxine hydrochloride.

22. Use of the dual release oral dosage form of any one of claims 1 to 21, for the preparation of a medicament for alleviating the symptoms of nausea and vomiting in a mammal.

23. Use of the dual release oral dosage form of any one of claims 1 to 21, for the preparation of a medicament for alleviating the symptoms of nausea and vomiting of human pregnancy.

24. The use of claim 21 or 22, wherein said dual release oral dosage form is for administration under fasted conditions.

25. The use of claim 21 or 22, wherein said dual release oral dosage form is for administration under fed conditions.

26. The use of any one of claims 21 to 25, wherein said dual release oral dosage form is for twice-a-day administration.

27. The dual release oral dosage form of any one of claims 1 to 21, for use in alleviating the symptoms of nausea and vomiting in a mammal.

28. The dual release oral dosage form of any one of claims 1 to 21, for use in alleviating the symptoms of nausea and vomiting of human pregnancy.

29. The dual release oral dosage form of claim 27 or 28, for administration under fasted conditions.

30. The dual release oral dosage form of claim 27 or 28, for administration under fed conditions.

31. The dual release oral dosage form of any one of claims 27 to 30, for twice-a-day administration.

32. A kit for use in alleviating the symptoms of nausea and vomiting in a mammal, said kit comprising the dual release oral dosage form of any one of claims 1 to 21 and a container.

33. The kit of claim 32, further comprising instructions for use of said dual release oral dosage form for alleviating the symptoms of nausea and vomiting in a mammal.

34. A kit for use in alleviating the symptoms of nausea and vomiting of human pregnancy, said kit comprising the dual release oral dosage form of any one of claims 1 to 21 and a container.

35. The kit of claim 34, further comprising instructions for use of said dual release oral dosage form for alleviating the symptoms of nausea and vomiting in human pregnancy.

36. The kit of any one of claims 32 to 35, further comprising instructions for administration of said dual release oral dosage form under fasted conditions.

37. The kit of any one of claims 32 to 35, further comprising instructions for administration of said dual release oral dosage form under fed conditions.