WHAT IS CLAIMED IS:

1. A dual release oral dosage form comprising:

(A) a core comprising a~~n~~ delayed~~immediate~~ release composition comprising:

(a) from about 5 mg to about 20 mg of doxylamine and/or a pharmaceutically acceptable salt thereof; and

(b) from about 5 mg to about 20 mg of one or more of (i) pyridoxine, (ii) a metabolite thereof selected from pyridoxine phosphate, pyridoxal, pyridoxal 5-phosphate, pyridoxamine, pyridoxamine 5-phosphate, (iii) a pharmaceutically acceptable ester of (i) or (ii) and/or (iv) a pharmaceutically acceptable salt of any of (i)-(iii); and

(B) a delayed release coat comprising a delayed release agent substantially surrounding said core; and

(C~~B~~) one or more immediate release coats substantially surrounding said delayed release coat and ~~a delayed release composition~~ comprising:

(a) from about 5 mg to about 20 mg of one or more of doxylamine and/or a pharmaceutically acceptable salt thereof; and

(b) from about 5 mg to about 20 mg of (i) pyridoxine, (ii) a metabolite thereof selected from pyridoxine phosphate, pyridoxal, pyridoxal 5-phosphate, pyridoxamine, pyridoxamine 5-phosphate, (iii) a pharmaceutically acceptable ester of (i) or (ii) and/or (iv) a pharmaceutically acceptable salt of any of (i)-(iii);

wherein said immediate release composition is for effecting release of the (a) doxylamine and/or pharmaceutically acceptable salt thereof, and (b) (i) pyridoxine, (ii) metabolite thereof, (iii) pharmaceutically acceptable ester of (i) or (ii) and/or (iv) pharmaceutically acceptable salt of any of (i)-(iii), which begins prior to release of the (a) doxylamine and/or pharmaceutically acceptable salt thereof, and (b) (i) pyridoxine, (ii) metabolite thereof, (iii) pharmaceutically acceptable ester of (i) or (ii) and/or (vi) pharmaceutically acceptable salt of any of (i)-(iii), from the delayed release composition, 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 doxylamine and/or pharmaceutically acceptable salt thereof.

5. The dual release oral dosage form of claim 4, wherein said dosage form comprises about 20 mg of doxylamine and/or pharmaceutically acceptable salt thereof.

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) metabolite thereof, (iii) pharmaceutically acceptable ester of (i) or (ii) and/or (iv) pharmaceutically acceptable salt of any of (i)-(iii).

7. The dual release oral dosage form of claim 6, wherein said dosage form comprises about 20 mg of (i) pyridoxine, (ii) metabolite thereof, (iii) pharmaceutically acceptable ester of (i) or (ii) and/or (iv) pharmaceutically acceptable salt of any of (i)-(iii).

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.~~10. The dual release oral dosage form of any one of claims 1~~0~~ to 9, wherein said delayed release coat comprises ~~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.~~11. The dual release oral dosage form of any one of claims 1 to 10~~2~~, wherein said immediate release composition, delayed release composition, or both, further comprise at least one pharmaceutically acceptable carrier or excipient.

~~14.~~12. The dual release oral dosage form of any one of claims 1 to 11~~3~~, where said immediate release composition comprises a pharmaceutically acceptable doxylamine salt and a pharmaceutically acceptable pyridoxine salt.

~~15.~~13. The dual release oral dosage form of any one of claims 1 to 12~~4~~, wherein said delayed release composition comprises a pharmaceutically acceptable doxylamine salt and a pharmaceutically acceptable pyridoxine salt.

~~16.~~14. The dual release oral dosage form of any one of claims 1 to 13~~5~~, where said dual release oral dosage form is a tablet.

~~17.~~15. The dual release oral dosage form of any one of claims 1 to 14~~6~~, wherein the amount of doxylamine and/or pharmaceutically acceptable salt thereof comprised in the immediate release composition is substantially equivalent to the amount of doxylamine and/or pharmaceutically acceptable salt thereof comprised in the delayed release composition.

~~18.~~16. The dual release oral form of any one of claims 1 to 15~~7~~, wherein the amount of (i) pyridoxine, (ii) metabolite thereof, (iii) pharmaceutically acceptable ester of (i) or (ii) and/or (iv) pharmaceutically acceptable salt of any of (i)-(iii) comprised in the immediate release composition is substantially equivalent to the amount of (i) pyridoxine, (ii) metabolite thereof, (iii) pharmaceutically acceptable ester of (i) or

(ii) and/or (iv) pharmaceutically acceptable salt of any of (i)-(iii) comprised in the delayed release composition.

~~19.~~17. The dual release oral dosage form of any one of claims 1 to 1~~6~~8, wherein said pharmaceutically acceptable doxylamine salt is doxylamine succinate.

~~20.~~18. The dual release oral dosage form of any one of claims 1 to 1~~7~~9, wherein said pharmaceutically acceptable pyridoxine salt is pyridoxine hydrochloride.

~~21.~~19. The dual release oral dosage form of any one of claims 1 to 18~~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.~~20. Use of the dual release oral dosage form of any one of claims 1 to 19~~21~~, for the preparation of a medicament for alleviating the symptoms of nausea and vomiting in a mammal.

~~23.~~21. Use of the dual release oral dosage form of any one of claims 1 to 19~~21~~, for the preparation of a medicament for alleviating the symptoms of nausea and vomiting of human pregnancy.

~~24.~~22. The use of claim 20 or 21~~ or 22~~, wherein said dual release oral dosage form is for administration under fasted conditions.

~~25.~~23. The use of claim 20 or 21~~ or 22~~, wherein said dual release oral dosage form is for administration under fed conditions.

~~26.~~24. The use of any one of claims 20~~1~~ to 23~~5~~, wherein said dual release oral dosage form is for twice-a-day administration.

~~27.~~25. The dual release oral dosage form of any one of claims 1 to 19~~21~~, for use in alleviating the symptoms of nausea and vomiting in a mammal.

~~28.~~26. The dual release oral dosage form of any one of claims 1 to 19~~21~~, for use in alleviating the symptoms of nausea and vomiting of human pregnancy.

~~29.~~27. The dual release oral dosage form of claim ~~27~~25 or 26~~28~~, for administration under fasted conditions.

~~30.~~28. The dual release oral dosage form of claim 25~~27~~ or 26~~28~~, for administration under fed conditions.

~~31.~~29. The dual release oral dosage form of any one of claims 25~~27~~ to 28~~30~~, for twice-a-day administration.

~~32.~~30. 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 19~~21~~ and a container.

~~33.~~31. The kit of claim 30~~2~~, further comprising instructions for use of said dual release oral dosage form for alleviating the symptoms of nausea and vomiting in a mammal.

~~34.~~32. 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 19~~21~~ and a container.

~~35.~~33. The kit of claim 32~~4~~, further comprising instructions for use of said dual release oral dosage form for alleviating the symptoms of nausea and vomiting in human pregnancy.

~~36.~~34. The kit of any one of claims 30~~2~~ to 33~~5~~, further comprising instructions for administration of said dual release oral dosage form under fasted conditions.

~~37.~~35. The kit of any one of claims 30~~2~~ to 33~~5~~, further comprising instructions for administration of 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 doxylamine and/or a pharmaceutically acceptable salt thereof; and

(b) from about 5 mg to about 20 mg of one or more of (i) pyridoxine, (ii) a metabolite thereof selected from pyridoxine phosphate, pyridoxal, pyridoxal 5-phosphate, pyridoxamine, pyridoxamine 5-phosphate, (iii) a pharmaceutically acceptable ester of (i) or (ii) and/or (iv) a pharmaceutically acceptable salt of any of (i)-(iii); and

(B) a delayed release composition comprising:

(a) from about 5 mg to about 20 mg of one or more of doxylamine and/or a pharmaceutically acceptable salt thereof; and

(b) from about 5 mg to about 20 mg of (i) pyridoxine, (ii) a metabolite thereof selected from pyridoxine phosphate, pyridoxal, pyridoxal 5-phosphate, pyridoxamine, pyridoxamine 5-phosphate, (iii) a pharmaceutically acceptable ester of (i) or (ii) and/or (iv) a pharmaceutically acceptable salt of any of (i)-(iii);

wherein said immediate release composition is for effecting release of the (a) doxylamine and/or pharmaceutically acceptable salt thereof, and (b) (i) pyridoxine, (ii) metabolite thereof, (iii) pharmaceutically acceptable ester of (i) or (ii) and/or (iv) pharmaceutically acceptable salt of any of (i)-(iii), which begins prior to release of the (a) doxylamine and/or pharmaceutically acceptable salt thereof, and (b) (i) pyridoxine, (ii) metabolite thereof, (iii) pharmaceutically acceptable ester of (i) or (ii) and/or (vi) pharmaceutically acceptable salt of any of (i)-(iii), from the delayed release composition, 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 doxylamine and/or pharmaceutically acceptable salt thereof.

5. The dual release oral dosage form of claim 4, wherein said dosage form comprises about 20 mg of doxylamine and/or pharmaceutically acceptable salt thereof.

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) metabolite thereof, (iii) pharmaceutically acceptable ester of (i) or (ii) and/or (iv) pharmaceutically acceptable salt of any of (i)-(iii).

7. The dual release oral dosage form of claim 6, wherein said dosage form comprises about 20 mg of (i) pyridoxine, (ii) metabolite thereof, (iii) pharmaceutically acceptable ester of (i) or (ii) and/or (iv) pharmaceutically acceptable salt of any of (i)-(iii).

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 doxylamine and/or pharmaceutically acceptable salt thereof comprised in the immediate release composition is substantially equivalent to the amount of doxylamine and/or pharmaceutically acceptable salt thereof 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) metabolite thereof, (iii) pharmaceutically acceptable ester of (i) or (ii) and/or (iv) pharmaceutically acceptable salt of any of (i)-(iii) comprised in the immediate release composition is substantially equivalent to the amount of (i) pyridoxine, (ii) metabolite thereof, (iii) pharmaceutically acceptable ester of (i) or (ii) and/or (iv) pharmaceutically acceptable salt of any of (i)-(iii) 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.

WHAT IS CLAIMED IS:

1. A dual release oral dosage form comprising:

(A) a core comprising a delayed release composition comprising:

(a) from about 5 mg to about 20 mg of doxylamine and/or a pharmaceutically acceptable salt thereof; and

(b) from about 5 mg to about 20 mg of one or more of (i) pyridoxine, (ii) a metabolite thereof selected from pyridoxine phosphate, pyridoxal, pyridoxal 5-phosphate, pyridoxamine, pyridoxamine 5-phosphate, (iii) a pharmaceutically acceptable ester of (i) or (ii) and/or (iv) a pharmaceutically acceptable salt of any of (i)-(iii); and

(B) a delayed release coat comprising a delayed release agent substantially surrounding said core; and

(C) one or more immediate release coats substantially surrounding said delayed release coat and comprising:

(a) from about 5 mg to about 20 mg of one or more of doxylamine and/or a pharmaceutically acceptable salt thereof; and

(b) from about 5 mg to about 20 mg of (i) pyridoxine, (ii) a metabolite thereof selected from pyridoxine phosphate, pyridoxal, pyridoxal 5-phosphate, pyridoxamine, pyridoxamine 5-phosphate, (iii) a pharmaceutically acceptable ester of (i) or (ii) and/or (iv) a pharmaceutically acceptable salt of any of (i)-(iii);

wherein said immediate release composition is for effecting release of the (a) doxylamine and/or pharmaceutically acceptable salt thereof, and (b) (i) pyridoxine, (ii) metabolite thereof, (iii) pharmaceutically acceptable ester of (i) or (ii) and/or (iv) pharmaceutically acceptable salt of any of (i)-(iii), which begins prior to release of the (a) doxylamine and/or pharmaceutically acceptable salt thereof, and (b) (i) pyridoxine, (ii) metabolite thereof, (iii) pharmaceutically acceptable ester of (i) or (ii) and/or (vi) pharmaceutically acceptable salt of any of (i)-(iii), from the delayed release composition, 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 doxylamine and/or pharmaceutically acceptable salt thereof.

5. The dual release oral dosage form of claim 4, wherein said dosage form comprises about 20 mg of doxylamine and/or pharmaceutically acceptable salt thereof.

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) metabolite thereof, (iii) pharmaceutically acceptable ester of (i) or (ii) and/or (iv) pharmaceutically acceptable salt of any of (i)-(iii).

7. The dual release oral dosage form of claim 6, wherein said dosage form comprises about 20 mg of (i) pyridoxine, (ii) metabolite thereof, (iii) pharmaceutically acceptable ester of (i) or (ii) and/or (iv) pharmaceutically acceptable salt of any of (i)-(iii).

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 delayed release coat comprises an enteric material.

11. The dual release oral dosage form of any one of claims 1 to 10, wherein said immediate release composition, delayed release composition, or both, further comprise at least one pharmaceutically acceptable carrier or excipient.

12. The dual release oral dosage form of any one of claims 1 to 11, where said immediate release composition comprises a pharmaceutically acceptable doxylamine salt and a pharmaceutically acceptable pyridoxine salt.

13. The dual release oral dosage form of any one of claims 1 to 12, wherein said delayed release composition comprises a pharmaceutically acceptable doxylamine salt and a pharmaceutically acceptable pyridoxine salt.

14. The dual release oral dosage form of any one of claims 1 to 13, where said dual release oral dosage form is a tablet.

15. The dual release oral dosage form of any one of claims 1 to 14, wherein the amount of doxylamine and/or pharmaceutically acceptable salt thereof comprised in the immediate release composition is substantially equivalent to the amount of doxylamine and/or pharmaceutically acceptable salt thereof comprised in the delayed release composition.

16. The dual release oral form of any one of claims 1 to 15, wherein the amount of (i) pyridoxine, (ii) metabolite thereof, (iii) pharmaceutically acceptable ester of (i) or (ii) and/or (iv) pharmaceutically acceptable salt of any of (i)-(iii) comprised in the immediate release composition is substantially equivalent to the amount of (i) pyridoxine, (ii) metabolite thereof, (iii) pharmaceutically acceptable ester of (i) or (ii) and/or (iv) pharmaceutically acceptable salt of any of (i)-(iii) comprised in the delayed release composition.

17. The dual release oral dosage form of any one of claims 1 to 16, wherein said pharmaceutically acceptable doxylamine salt is doxylamine succinate.

18. The dual release oral dosage form of any one of claims 1 to 17, wherein said pharmaceutically acceptable pyridoxine salt is pyridoxine hydrochloride.

19. The dual release oral dosage form of any one of claims 1 to 18, 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.

20. Use of the dual release oral dosage form of any one of claims 1 to 19, for the preparation of a medicament for alleviating the symptoms of nausea and vomiting in a mammal.

21. Use of the dual release oral dosage form of any one of claims 1 to 19, for the preparation of a medicament for alleviating the symptoms of nausea and vomiting of human pregnancy.

22. The use of claim 20 or 21, wherein said dual release oral dosage form is for administration under fasted conditions.

23. The use of claim 20 or 21, wherein said dual release oral dosage form is for administration under fed conditions.

24. The use of any one of claims 20 to 23, wherein said dual release oral dosage form is for twice-a-day administration.

25. The dual release oral dosage form of any one of claims 1 to 19, for use in alleviating the symptoms of nausea and vomiting in a mammal.

26. The dual release oral dosage form of any one of claims 1 to 19, for use in alleviating the symptoms of nausea and vomiting of human pregnancy.

27. The dual release oral dosage form of claim 25 or 26, for administration under fasted conditions.

28. The dual release oral dosage form of claim 25 or 26, for administration under fed conditions.

29. The dual release oral dosage form of any one of claims 25 to 28, for twice-a-day administration.

30. 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 19 and a container.

31. The kit of claim 30, further comprising instructions for use of said dual release oral dosage form for alleviating the symptoms of nausea and vomiting in a mammal.

32. 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 19 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 human pregnancy.

34. The kit of any one of claims 30 to 33, further comprising instructions for administration of said dual release oral dosage form under fasted conditions.

35. The kit of any one of claims 30 to 33, further comprising instructions for administration of said dual release oral dosage form under fed conditions.