WE CLAIM:

1. A pharmaceutical formulation comprising trans-1{4-[2-[4-(2,3-dichlorophenyl)-piperazin-1-yl]-ethyl]-cyclohexyl}-3,3-dimethyl-urea, or a pharmaceutically acceptable salt thereof, wherein the formulation comprises less than about 1 % w/w trans-4-[2-[4-(2,3-dichlorophenyl)-piperazin-1-yl]-ethyl]-cyclohexyl-amine, or a pharmaceutically acceptable salt thereof.

2. A pharmaceutical formulation comprising from about 0.05 to about 15 mg trans-1{4-[2-[4-(2,3-dichlorophenyl)-piperazin-1-yl]-ethyl]-cyclohexyl}-3,3-dimethyl-urea, or a pharmaceutically acceptable salt thereof, wherein the formulation provides an *in vivo* plasma profile comprising:

(i) a mean C_{max} of less than about 26.3 ng/mL,
(ii) a mean $AUC_{0-\infty}$ of more than about 2 ng.hr/mL and
(iii) a mean T_{max} of about 3 or more hours.

3. The formulation of claim 2, wherein the formulation comprises about 0.1 mg trans-1{4-[2-[4-(2,3-dichlorophenyl)-piperazin-1-yl]-ethyl]-cyclohexyl}-3,3-dimethyl-urea, or a pharmaceutically acceptable salt thereof, and provides an *in vivo* plasma profile comprising:

(i) a mean C_{max} of less than about 0.2 ng/mL,

(ii) a mean $AUC_{0-\infty}$ of more than about 2 ng.hr/mL and

(iii) a mean T_{max} of about 3 or more hours.

4. The formulation of claim 2, wherein the formulation comprises about 0.25 mg trans-1{4-[2-[4-(2,3-dichlorophenyl)-piperazin-1-yl]-ethyl]-cyclohexyl}-3,3-dimethyl-urea, or a pharmaceutically acceptable salt thereof, and provides an *in vivo* plasma profile comprising:

(i) a mean C_{max} of less than about 0.5 ng/mL,

(ii) a mean $AUC_{0-\infty}$ of more than about 5 ng.hr/mL and

(iii) a mean T_{max} of about 3 or more hours.

5. The formulation of claim 2, wherein the formulation comprises about 0.5 mg trans-1{4-[2-[4-(2,3-dichlorophenyl)-piperazin-1-yl]-ethyl]-cyclohexyl}-3,3-dimethyl-urea, or a pharmaceutically acceptable salt thereof, and provides an *in vivo* plasma profile comprising:

(i) a mean C_{max} of less than about 0.9 ng/mL,

(ii) a mean $AUC_{0-\infty}$ of more than about 10 ng.hr/mL and

(iii) a mean T_{max} of about 3 or more hours.

6. The formulation of claim 2, wherein the formulation comprises about 1 mg trans-1{4-[2-[4-(2,3-dichlorophenyl)-piperazin-1-yl]-ethyl]-cyclohexyl}-3,3-dimethyl-urea, or a pharmaceutically acceptable salt thereof, and provides an *in vivo* plasma profile comprising:

(i) a mean C_{max} of less than about 1.8 ng/mL,

(ii) a mean $AUC_{0-\infty}$ of more than about 20 ng.hr/mL and

(iii) a mean T_{max} of about 3 or more hours.

7. The formulation of claim 2, wherein the formulation comprises about 1.5 mg trans-1{4-[2-[4-(2,3-dichlorophenyl)-piperazin-1-yl]-ethyl]-cyclohexyl}-3,3-dimethyl-urea, or a pharmaceutically acceptable salt thereof, and provides an *in vivo* plasma profile comprising:

(i) a mean C_{max} of less than about 2.7 ng/mL,

(ii) a mean $AUC_{0-\infty}$ of more than about 30 ng.hr/mL and

(iii) a mean T_{max} of about 3 or more hours.

8. The formulation of claim 2, wherein the formulation comprises about 2 mg trans-1{4-[2-[4-(2,3-dichlorophenyl)-piperazin-1-yl]-ethyl]-cyclohexyl}-3,3-dimethyl-urea, or a pharmaceutically acceptable salt thereof, and provides an *in vivo* plasma profile comprising:

(i) a mean C_{max} of less than about 3.5 ng/mL,

(ii) a mean $AUC_{0-\infty}$ of more than about 40 ng.hr/mL and

(iii) a mean T_{max} of about 3 or more hours.

9. The formulation of claim 2, wherein the formulation comprises about 2.5 mg trans-1{4-[2-[4-(2,3-dichlorophenyl)-piperazin-1-yl]-ethyl]-cyclohexyl}-3,3-dimethyl-urea, or a pharmaceutically acceptable salt thereof, and provides an *in vivo* plasma profile comprising:

(i) a mean C_{max} of less than about 4.4 ng/mL,

(ii) a mean $AUC_{0-\infty}$ of more than about 50 ng.hr/mL and

(iii) a mean T_{max} of about 3 or more hours.

10. The formulation of claim 2, wherein the formulation comprises about 3 mg trans-1{4-[2-[4-(2,3-dichlorophenyl)-piperazin-1-yl]-ethyl]-cyclohexyl}-3,3-dimethyl-urea, or a pharmaceutically acceptable salt thereof, and provides an *in vivo* plasma profile comprising:

(i) a mean C_{max} of less than about 5.3 ng/mL,

(ii) a mean $AUC_{0-\infty}$ of more than about 60 ng.hr/mL and

(iii) a mean T_{max} of about 3 or more hours.

11. The formulation of claim 2, wherein the formulation comprises about 4.5 mg trans-1{4-[2-[4-(2,3-dichlorophenyl)-piperazin-1-yl]-ethyl]-cyclohexyl}-3,3-dimethyl-urea, or a pharmaceutically acceptable salt thereof, and provides an *in vivo* plasma profile comprising:

(i) a mean C_{max} of less than about 7.9 ng/mL,

(ii) a mean $AUC_{0-\infty}$ of more than about 90 ng.hr/mL and

(iii) a mean T_{max} of about 3 or more hours.

12. The formulation of claim 2, wherein the formulation comprises about 5 mg trans-1{4-[2-[4-(2,3-dichlorophenyl)-piperazin-1-yl]-ethyl]-cyclohexyl}-3,3-dimethyl-urea, or a pharmaceutically acceptable salt thereof, and provides an *in vivo* plasma profile comprising:

(i) a mean C_{max} of less than about 8.8 ng/mL,

(ii) a mean $AUC_{0-\infty}$ of more than about 100 ng.hr/mL and

(iii) a mean T_{max} of about 3 or more hours.

13. The formulation of claim 2, wherein the formulation comprises about 6 mg trans-1{4-[2-[4-(2,3-dichlorophenyl)-piperazin-1-yl]-ethyl]-cyclohexyl}-3,3-dimethyl-urea, or a pharmaceutically acceptable salt thereof, and provides an *in vivo* plasma profile comprising:

(i) a mean C_{max} of less than about 10.5 ng/mL,

(ii) a mean $AUC_{0-\infty}$ of more than about 120 ng.hr/mL and

(iii) a mean T_{max} of about 3 or more hours.

14. The formulation of claim 2, wherein the formulation comprises about 7.5 mg trans-1{4-[2-[4-(2,3-dichlorophenyl)-piperazin-1-yl]-ethyl]-cyclohexyl}-3,3-dimethyl-urea, or a pharmaceutically acceptable salt thereof, and provides an *in vivo* plasma profile comprising:

(i) a mean C_{max} of less than about 13.2 ng/mL,

(ii) a mean $AUC_{0-\infty}$ of more than about 150 ng.hr/mL and

(iii) a mean T_{max} of about 3 or more hours.

15. The formulation of claim 2, wherein the formulation comprises about 9 mg trans-1{4-[2-[4-(2,3-dichlorophenyl)-piperazin-1-yl]-ethyl]-cyclohexyl}-3,3-dimethyl-urea, or a pharmaceutically acceptable salt thereof, and provides an *in vivo* plasma profile comprising:

(i) a mean C_{max} of less than about 15.8 ng/mL,

(ii) a mean $AUC_{0-\infty}$ of more than about 180 ng.hr/mL and

(iii) a mean T_{max} of about 3 or more hours.

16. The formulation of claim 2, wherein the formulation comprises about 12.5 mg trans-1{4-[2-[4-(2,3-dichlorophenyl)-piperazin-1-yl]-ethyl]-cyclohexyl}-3,3-dimethyl-urea, or a pharmaceutically acceptable salt thereof, and provides an *in vivo* plasma profile comprising:

(i) a mean C_{max} of less than about 21.9 ng/mL,

(ii) a mean $AUC_{0-\infty}$ of more than about 250 ng.hr/mL and

(iii) a mean T_{max} of about 3 or more hours.

17. The formulation of claim 2, wherein the formulation comprises about 15 mg trans-1{4-[2-[4-(2,3-dichlorophenyl)-piperazin-1-yl]-ethyl]-cyclohexyl}-3,3-dimethyl-urea, or a pharmaceutically acceptable salt thereof, and provides an *in vivo* plasma profile comprising:

(i) a mean C_{max} of less than about 26.3 ng/mL,

(ii) a mean $AUC_{0-\infty}$ of more than about 300 ng.hr/mL and

(iii) a mean T_{max} of about 3 or more hours.

18. The formulation as in either claim 1 or claim 2, wherein the formulation comprises trans-1{4-[2-[4-(2,3-dichlorophenyl)-piperazin-1-yl]-ethyl]-cyclohexyl}-3,3-dimethyl-urea hydrochloride.

19. A pharmaceutical formulation comprising:

(a) between about 0.5 % and about 15 % of trans-1{4-[2-[4-(2,3-dichlorophenyl)-piperazin-1-yl]-ethyl]-cyclohexyl}-3,3-dimethyl-urea hydrochloride,

(b) between about 5 % and about 95 % of lactose monohydrate,

(c) between 0 % and about 10 % of talc,

(d) between 0 % and about 5 % of colloidal silicon dioxide,

(e) between 0 % and about 15 % of sodium starch glycolate,

(f) between 0 % and about 15 % of hydroxypropyl cellulose, and

(g) between about 0.1 % and about 3 % of magnesium stearate.

20. A pharmaceutical formulation comprising:

(a) between about 0.5 % and about 15 % of trans-1{4-[2-[4-(2,3-dichlorophenyl)-piperazin-1-yl]-ethyl]-cyclohexyl}-3,3-dimethyl-urea hydrochloride,

(b) between about 0.1 % and about 20 % of sodium carbonate,

(c) between 0 % and about 10 % of talc,

(d) between 0 % and about 5 % of colloidal silicon dioxide,

(e) between 0 % and about 15 % of sodium starch glycolate,

(f) between about 5 % and about 95 % of microcrystalline cellulose, and

(g) between about 0.1 % and about 3 % of magnesium stearate.

21. The pharmaceutical formulation as in either claim 19 or claim 20, wherein the formulation comprises less than about 1 % w/w trans-4-[2-[4-(2,3-dichlorophenyl)-piperazin-1-yl]-ethyl]-cyclohexyl-amine, or a pharmaceutically acceptable salt thereof.

22. The pharmaceutical formulation as in either claim 1 or claim 2, wherein the formulation releases trans-1{4-[2-[4-(2,3-dichlorophenyl)-piperazin-1-yl]-ethyl]-cyclohexyl}-

3,3-dimethyl-urea, or a pharmaceutically acceptable salt thereof, at a rate of more than about 80 % within about the first 60 minutes following administration of the formulation to a patient in need thereof.

23. A method of treating a condition that requires modulation of a dopamine receptor comprising administering to a patient in need thereof an effective amount of a formulation of claim 1.

24. The method of claim 23, wherein the condition is schizophrenia.

25. The method of claim 23, wherein the condition is bipolar disorder.

26. The method of claim 23, wherein the disorder is acute mania.

Claims

1. A pharmaceutical formulation in a solid oral dosage form comprising trans-1{4-[2-[4-(2,3-dichlorophenyl)-piperazin-1-yl]-ethyl]-cyclohexyl}-3,3-dimethyl-urea, or a pharmaceutically acceptable salt thereof, a buffering agent or an excipient selected from pregelatinized starch and anhydrous calcium hydrogen phosphate, and wherein the formulation comprises less than about 1 % w/w trans-4-[2-[4-(2,3-dichlorophenyl)-piperazin-1-yl]-ethyl]-cyclohexyl-amine, or a pharmaceutically acceptable salt thereof.

2. The formulation of claim 1, comprising from about 0.5 to about 15 mg trans-1{4-[2-[4-(2,3-dichlorophenyl)-piperazin-1-yl]-ethyl]-cyclohexyl}-3,3-dimethyl-urea, or a pharmaceutically acceptable salt thereof, wherein the formulation provides an in vivo plasma profile comprising:

   (i) a mean C_{max} of less than about 26.3 ng/mL,
   (ii) a mean $AUC_{0-\infty}$ of more than about 10 ng.hr/mL and
   (iii) a mean T_{max} of about 3 or more hours.

3. The formulation of claim 2, wherein the formulation comprises about 0.5 mg trans-1{4-[2-[4-(2,3-dichlorophenyl)-piperazin-1-yl]-ethyl]-cyclohexyl}-3,3-dimethyl-urea, or a pharmaceutically acceptable salt thereof, and provides an in vivo plasma profile comprising:

   (i) a mean C_{max} of less than about 0.9 ng/mL,
   (ii) a mean $AUC_{0-\infty}$ of more than about 10 ng.hr/mL and
   (iii) a mean T_{max} of about 3 or more hours.

4. The formulation of claim 2, wherein the formulation comprises about 1 mg trans-1{4-[2-[4-(2,3-dichlorophenyl)-piperazin-1-yl]-ethyl]-cyclohexyl}-3,3-dimethyl-urea, or a pharmaceutically acceptable salt thereof, and provides an in vivo plasma profile comprising:

   (i) a mean C_{max} of less than about 1.8 ng/mL,
   (ii) a mean $AUC_{0-\infty}$ of more than about 20 ng.hr/mL and
   (iii) a mean T_{max} of about 3 or more hours.

5. The formulation of claim 2, wherein the formulation comprises about 1.5 mg trans-1{4-[2-[4-(2,3-dichlorophenyl)-piperazin-1-yl]-ethyl]-cyclohexyl}-3,3-dimethyl-urea, or a pharmaceutically acceptable salt thereof, and provides an in vivo plasma profile comprising:

   (i) a mean C_{max} of less than about 2.7 ng/mL,
   (ii) a mean $AUC_{0-\infty}$ of more than about 30 ng.hr/mL and
   (iii) a mean T_{max} of about 3 or more hours.

6. The formulation of claim 2, wherein the formulation comprises about 2 mg trans-1{4-[2-[4-(2,3-dichlorophenyl)-piperazin-1-yl]-ethyl]-cyclohexyl}-3,3-dimethyl-urea, or a pharmaceutically acceptable salt thereof, and provides an in vivo plasma profile comprising:

   (i) a mean C_{max} of less than about 3.5 ng/mL,
   (ii) a mean $AUC_{0-\infty}$ of more than about 40 ng.hr/mL and
   (iii) a mean T_{max} of about 3 or more hours.

7. The formulation of claim 2, wherein the formulation comprises about 2.5 mg trans-1{4-[2-[4-(2,3-dichlorophenyl)-piperazin-1-yl]-ethyl]-cyclohexyl}-3,3-dimethyl-urea, or a pharmaceutically acceptable salt thereof, and provides an in vivo plasma profile comprising:

   (i) a mean C_{max} of less than about 4.4 ng/mL,
   (ii) a mean $AUC_{0-\infty}$ of more than about 50 ng.hr/mL and
   (iii) a mean T_{max} of about 3 or more hours.

8. The formulation of claim 2, wherein the formulation comprises about 3 mg trans-1{4-[2-[4-(2,3-dichlorophenyl)-piperazin-1-yl]-ethyl]-cyclohexyl}-3,3-dimethyl-urea, or a pharmaceutically acceptable salt thereof, and provides an in vivo plasma profile comprising:

   (i) a mean C_{max} of less than about 5.3 ng/mL,
   (ii) a mean $AUC_{0-\infty}$ of more than about 60 ng.hr/mL and
   (iii) a mean T_{max} of about 3 or more hours.

9. The formulation of claim 2, wherein the formulation comprises about 6 mg trans-1{4-[2-[4-(2,3-dichlorophenyl)-piperazin-1-yl]-ethyl]-cyclohexyl}-3,3-dimethyl-urea, or a pharmaceutically acceptable salt thereof, and provides an in vivo plasma profile comprising:

   (i) a mean C_{max} of less than about 10.5 ng/mL,
   (ii) a mean $AUC_{0-\infty}$ of more than about 120 ng.hr/mL and
   (iii) a mean T_{max} of about 3 or more hours.

10. The formulation of claim 2, wherein the formulation comprises about 9 mg trans-1{4-[2-[4-(2,3-dichlorophenyl)-piperazin-1-yl]-ethyl]-cyclohexyl}-3,3-dimethyl-urea, or a pharmaceutically acceptable salt thereof, and provides an in vivo plasma profile comprising:

    (i) a mean C_{max} of less than about 15.8 ng/mL,
    (ii) a mean $AUC_{0-\infty}$ of more than about 180 ng.hr/mL and
    (iii) a mean T_{max} of about 3 or more hours.

11. The formulation of claim 2, wherein the formulation comprises about 12.5 mg trans-1{4-[2-[4-(2,3-dichlorophenyl)-piperazin-1-yl]-ethyl]-cyclohexyl}-3,3-dimethyl-urea, or a pharmaceutically acceptable salt thereof, and provides an in vivo plasma profile comprising:

    (i) a mean C_{max} of less than about 21.9 ng/mL,
    (ii) a mean $AUC_{0-\infty}$ of more than about 250 ng.hr/mL and
    (iii) a mean T_{max} of about 3 or more hours.

12. The formulation as in either claim 1 or claim 2, wherein the formulation comprises trans-1{4-[2-[4-(2,3-dichlorophenyl)-piperazin-1-yl]-ethyl]-cyclohexyl}-3,3-dimethyl-urea hydrochloride.

13. The formulation as in either claim 1 or claim 2, comprising:

    (a) between about 0.5 % and about 15 % of trans-1{4-[2-[4-(2,3-dichlorophenyl)-piperazin-1-yl]-ethyl]-cyclohexyl}-3,3-dimethyl-urea hydrochloride,
    (b) between about 0.1 % and about 20 % of sodium carbonate,
    (c) between 0 % and about 10 % of talc,
    (d) between 0 % and about 5 % of colloidal silicon dioxide,

(e) between 0 % and about 15 % of sodium starch glycolate,
(f) between about 5 % and about 95 % of microcrystalline cellulose, and
(g) between about 0.1 % and about 3 % of magnesium stearate.

14. The formulation as in either claim 1 or claim 2, wherein the formulation releases trans-1{4-[2-[4-(2,3-dichlorophenyl)-piperazin-1-yl]-ethyl]-cyclohexyl}-3,3-dimethyl-urea, or a pharmaceutically acceptable salt thereof, at a rate of more than about 80 % within about the first 60 minutes following administration of the formulation to a patient in need thereof.

15. The formulation as in either claim 1 or claim 2 for use in a method of treating schizophrenia, bipolar disorder or acute mania.