CLAIMS

1. An oral pharmaceutical formulation, comprising L-ornithine phenylacetate in an oral dosage of about 0.1 g to about 10 g, and one or more pharmaceutically acceptable excipients or carriers.

2. The oral pharmaceutical formulation of Claim 0, wherein the formulation provides an immediate release profile of L-ornithine phenylacetate upon oral administration.

3. The oral pharmaceutical formulation of Claim 1, wherein the oral dosage of L-ornithine phenylacetate is about 2.5 g.

4. The oral pharmaceutical formulation of Claim 1, wherein the oral dosage of L-ornithine phenylacetate is about 5 g.

5. The oral pharmaceutical formulation of any one of Claims 0 to 4, wherein the formulation is in a single unit dosage form.

6. The oral pharmaceutical formulation of any one of Claims 0 to 5, wherein the formulation is in two or more unit dosage forms.

7. The oral pharmaceutical formulation of Claims 6, wherein the unit dosage form is a tablet, a capsule, a pill, pellets, free-flowing powder, or liquid.

8. The oral pharmaceutical formulation of Claim 7, wherein the unit dosage form is a liquid solution.

9. The oral pharmaceutical formulation of any one of Claims 0 to 8, wherein the formulation provides conversion of phenylacetate to phenylacetylglutamine of greater than about 30% over 24 hours.

10. The oral pharmaceutical formulation of Claim 9, wherein the formulation provides conversion of phenylacetate to phenylacetylglutamine of greater than about 50% over 24 hours.

11. The oral pharmaceutical formulation of Claim 10, wherein the formulation provides conversion of phenylacetate to phenylacetylglutamine of greater than about 80% over 24 hours.

12. Use of an oral pharmaceutical formulation according to any one of Claims 0 to 11 in the preparation of a medicament for treating or ameliorating hyperammonemia in a subject.

13. The use of Claim 12, wherein said oral pharmaceutical formulation provides a plasma Cmax of phenylacetic acid from about 10 μg/mL to about 120 μg/mL.

14. The use of Claim 13, wherein the plasma Cmax of phenylacetic acid is from about 20 μg/mL to about 110 μg/mL.

15. The use of any one of Claims 12 to 14, wherein said oral pharmaceutical formulation provides a plasma Cmax of phenylacetylglutamine from about 10 μg/mL to about 80 μg/mL.

16. The use of Claim 15, wherein the plasma Cmax of phenylacetylglutamine is from about 20 μg/mL to about 45 μg/mL.

17. Use of an oral pharmaceutical formulation comprising L-ornithine phenylacetate in the preparation of a medicament for treating or ameliorating hyperammonemia in a subject, wherein said oral pharmaceutical formulation provides a plasma Cmax of phenylacetic acid ranging from about 10 μg/mL to about 150 μg/mL.

18. The use of Claim 17, wherein the plasma Cmax level of phenylacetic acid is from about 20 μg/mL to about 140 μg/mL.

19. The use of Claim 18, wherein the plasma Cmax level of phenylacetic acid is from about 30 μg/mL to about 130 μg/mL.

20. The use of Claim 19, wherein the plasma Cmax level of phenylacetic acid is from about 40 μg/mL to about 120 μg/mL.

21. The use of any one of Claims 17 to 20, wherein the oral pharmaceutical formulation provides a plasma Cmax of phenylacetylglutamine ranging from about 5 μg/mL to about 100 μg/mL.

22. The use of Claim 21, wherein the plasma Cmax of phenylacetylglutamine is from about 10 μg/mL to about 80 μg/mL.

23. The use of Claim 22, wherein the plasma Cmax of phenylacetylglutamine is from about 20 μg/mL to about 60 μg/mL.

24. The use of Claim 23, wherein the plasma Cmax of phenylacetylglutamine is from about 25 μg/mL to about 50 μg/mL.

25. Use of an oral pharmaceutical formulation comprising L-ornithine phenylacetate in the preparation of a medicament for treating or ameliorating hyperammonemia in a subject, wherein said oral pharmaceutical formulation provides a plasma $AUC_{0\text{-}t}$ or $AUC_{0\text{-}inf}$ of phenylacetic acid ranging from about 100 hr*μg/mL to about 1000 hr*μg/mL.

26. The use of Claim 25, wherein the plasma AUC_{0-t} or AUC_{0-inf} of phenylacetic acid is from about 200 hr*μg/mL to about 800 hr*μg/mL.

27. The use of Claim 26, wherein the plasma AUC_{0-t} or AUC_{0-inf} of phenylacetic acid is from about 350 hr*μg/mL to about 600 hr*μg/mL.

28. The use of Claim 26, wherein the plasma AUC_{0-t} or AUC_{0-inf} of phenylacetic acid is from about 400 hr*μg/mL to about 550 hr*μg/mL.

29. The use of any one of Claims 25 to 28, wherein the plasma AUC_{0-t} or AUC_{0-inf} of phenylacetylglutamine is from about 25 hr*μg/mL to about 500 hr*μg/mL.

30. The use of Claim 29, wherein the plasma AUC_{0-t} of phenylacetylglutamine is from about 50 hr*μg/mL to about 300 hr*μg/mL.

31. The use of Claim 30, wherein the plasma AUC_{0-t} of phenylacetylglutamine is from about 100 hr*μg/mL to about 200 hr*μg/mL.

32. The use of Claim 31, wherein the plasma AUC_{0-t} of phenylacetylglutamine is from about 120 hr*μg/mL to about 180 hr*μg/mL.

33. The use of Claim 29, wherein the plasma AUC_{0-inf} of phenylacetylglutamine is from about 50 hr*μg/mL to about 400 hr*μg/mL.

34. The use of Claim 33, wherein the plasma AUC_{0-inf} of phenylacetylglutamine is from about 75 hr*μg/mL to about 300 hr*μg/mL.

35. The use of Claim 34, wherein the plasma AUC_{0-inf} of phenylacetylglutamine is from about 100 hr*μg/mL to about 250 hr*μg/mL.

36. The use of Claim 35, wherein the plasma AUC_{0-inf} of phenylacetylglutamine is from about 150 hr*μg/mL to about 200 hr*μg/mL.

37. The use of any one of Claim 25 to 36, wherein the pharmaceutical formulation is selected from any one of Claims 0 to 11.

38. The use of any one of Claims 12 to 37, wherein the subject has acute liver failure or chronic liver disease.

39. The use of Claim 38, wherein the subject has liver cirrhosis or liver decompensation.

40. The use of Claim 38 or 39, wherein the chronic liver disease or liver cirrhosis has a classification of Child-Pugh class A, B or C.

41. The use of any one of Claims 12 to 37, wherein the subject has hepatic encephalopathy.

42. The use of any one of Claims 12 to 37, wherein the subject has portal hypertension.

43. The use of any one of Claims 12 to 37, wherein the subject has a urea cycle disorder.

44. The use of any one of Claims 12 to 43, wherein the oral pharmaceutical formulation provides an immediate release of L-ornithine phenylacetate.

45. The use of any one of Claims 12 to 44, wherein said oral pharmaceutical formulation is for administration at least once a day.

46. The use of any one of Claims 12 to 45, wherein said oral pharmaceutical formulation is for administration two or more times a day.

47. The use of any one of Claims 12 to 46, wherein said oral pharmaceutical formulation provides conversion of phenylacetate to phenylacetylglutamine of greater than about 30% over 24 hours.

48. The use of Claim 47, wherein said oral pharmaceutical formulation provides conversion of phenylacetate to phenylacetylglutamine of greater than about 50% over 24 hours.

49. The use of Claim 48, wherein said oral pharmaceutical formulation provides conversion of phenylacetate to phenylacetylglutamine of greater than about 80% over 24 hours.

50. The use of any one of Claims 12 to 49, wherein the oral pharmaceutical formulation comprises 1 to 5 unit dosage forms each comprising from about 0.1 g to about 2 g of L-ornithine phenylacetate.

51. The use of any one of Claims 12 to 50, wherein the oral pharmaceutical formulation comprises 2 to 4 unit dosage forms each comprising from about 0.5 g to about 1.25 g of L-ornithine phenylacetate.