CLAIMS

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

2. The oral pharmaceutical formulation of Claim 1, wherein the oral dosage of L-ornithine phenylacetate is about 3 g to about 10 g.

3. The oral pharmaceutical formulation of any one of Claims 1 or 2, wherein the oral dosage of L-ornithine phenylacetate is about 4 g to about 6 g.

4. The oral pharmaceutical formulation of any one of Claims 1 to 3, wherein the oral dosage of L-ornithine phenylacetate is about 5 g.

5. The oral pharmaceutical formulation of any one of Claims 0 to 3, wherein the formulation is in a single unit dosage form.

6. The oral pharmaceutical formulation of any one of Claims 0 to 4, wherein the formulation is in two or more unit dosage forms.

7. The oral pharmaceutical formulation of claim 6, comprising 2 to 5 units dosage forms, each comprising about 0.5 g to about 2 g L-ornithine phenylacetate.

8. The oral pharmaceutical formulation of any one of Claims 5 to 7, wherein the unit dosage form is a tablet, a capsule, a pill, pellets, free-flowing powder, or liquid.

9. The oral pharmaceutical formulation of any one of Claims 1 to 8, wherein the formulation provides an immediate release profile of L-ornithine phenylacetate upon oral administration.

10. Use of an oral pharmaceutical formulation according to any one of Claims 0 to 9 in the preparation of a medicament for treating or ameliorating hyperammonemia in a subject.

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

12. The use of Claim 10 or 11, wherein said oral pharmaceutical formulation provides a plasma Cmax of phenylacetylglutamine from about 10 μg/mL to about 80 μg/mL.

13. 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 comprises about 3 g to about 10 g L-ornithine

phenylacetate, and provides a plasma Cmax of phenylacetic acid ranging from about 10 μg/mL to about 150 μg/mL.

14. The use of Claim 13, wherein the plasma Cmax level of phenylacetic acid is from about 40 μg/mL to about 120 μg/mL.

15. The use of Claim 13 or 14, wherein the oral pharmaceutical formulation provides a plasma Cmax of phenylacetylglutamine ranging from about 5 μg/mL to about 100 μg/mL.

16. The use of Claim 15, wherein the plasma Cmax of phenylacetylglutamine is from about 25 μg/mL to about 50 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 comprises about 3 g to about 10 g L-ornithine phenylacetate, and 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.

18. The use of Claim 17, wherein the plasma $AUC_{0\text{-}t}$ or $AUC_{0\text{-}inf}$ of phenylacetic acid is from about 400 hr*μg/mL to about 550 hr*μg/mL.

19. The use of Claim 17 or 18, wherein the plasma $AUC_{0\text{-}t}$ or $AUC_{0\text{-}inf}$ of phenylacetylglutamine is from about 25 hr*μg/mL to about 500 hr*μg/mL.

20. The use of Claim 19, wherein the plasma $AUC_{0\text{-}t}$ of phenylacetylglutamine is from about 120 hr*μg/mL to about 180 hr*μg/mL.

21. The use of Claim 19, wherein the plasma $AUC_{0\text{-}inf}$ of phenylacetylglutamine is from about 150 hr*μg/mL to about 200 hr*μg/mL.

22. The use of any one of Claims 10 to 21, wherein the subject has acute liver failure or chronic liver disease.

23. The use of Claim 22, wherein the subject has liver cirrhosis or liver decompensation, and wherein the liver cirrhosis has a classification of Child-Pugh class A, B or C.

24. The use of any one of Claims 10 to 21, wherein the subject has one or more conditions selected from the group consisting of hepatic encephalopathy, portal hypertension, and urea cycle disorder.

25. The use of any one of Claims 10 to 24, wherein the oral pharmaceutical formulation provides an immediate release of L-ornithine phenylacetate.

26. The use of any one of Claims 10 to 25, wherein said oral pharmaceutical formulation is for administration at least once a day.

27. The use of any one of Claims 10 to 26, wherein said oral pharmaceutical formulation provides conversion of phenylacetate to phenylacetylglutamine of greater than about 80% over 24 hours.

28. The use of any one of Claims 10 to 27, wherein the oral pharmaceutical formulation comprises about 4 g to about 6 g L-ornithine phenylacetate.

29. The use of claim 28, wherein the oral pharmaceutical formulation comprises 3 to 6 unit dosage forms each comprising from about 0.5 g to about 1 g of L-ornithine phenylacetate.

30. The use of any one of Claims 10 to 29, wherein the oral pharmaceutical formulation is for administration three times a day.