CLAIMS

~~1. A product comprising an oral pharmaceutical formulation of L-ornithine phenylacetate in a daily dosage of 8 g to 15 g.~~

~~2. The product of Claim 1, wherein the daily dosage of L-ornithine phenylacetate is 8 g to 12 g.~~

~~3. The product of Claim 1 or 2, wherein the daily dosage of L-ornithine phenylacetate is in a single unit dosage form.~~

~~4. The product of Claim 1 or 2, wherein the daily dosage of L-ornithine phenylacetate is in two or more unit dosage forms.~~

~~5. The product of any one of Claims 3 or 4, wherein the unit dosage form is a tablet, a capsule, a pill, pellets, free-flowing powder, or liquid.~~

~~6. The product of any one of Claims 1 to 5, wherein the oral pharmaceutical formulation provides an immediate release profile of L-ornithine phenylacetate upon oral administration.~~

~~7.~~1. Use of an oral pharmaceutical formulation ~~of~~ comprising L-ornithine phenylacetate in the preparation of a medicament for treating or ameliorating hyperammonemia in a subject, wherein the medicament comprises a daily dose of 8 g to ~~15~~ 12 g L-ornithine phenylacetate.

~~8. The use of Claim 7, wherein the medicament comprises a daily dose of 8 g to 12 g L-ornithine phenylacetate.~~

2. The use of Claim 1, wherein the medicament is for administration once a day.

3. The use of Claim 1, wherein the medicament comprises 4 g to 6 g L-ornithine phenylacetate for administration twice a day.

4. The use of Claim 3, wherein the 4 g to 6 g of L-ornithine phenylacetate is in a single unit dosage form.

5. The use of Claim 3, wherein the 4 g to 6 g of L-ornithine phenylacetate is in two or more unit dosage forms.

6. The use of Claim 5, wherein the 4 g to 6 g L-ornithine phenylacetate is in 4 to 6 unit dosage forms each comprising 1 g L-ornithine phenylacetate.

~~9.~~7. The use of ~~Claim 7 or 8~~any one of Claims 1 to 6, wherein said oral pharmaceutical formulation provides a plasma Cmax of phenylacetic acid from 10 μg/mL to 120 μg/mL.

~~10.~~8. The use of any one of Claims ~~7 to 9~~1 to 7, wherein said oral pharmaceutical formulation provides a plasma Cmax of phenylacetylglutamine from 10 μg/mL to 80 μg/mL.

~~11.~~9. 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 the medicament comprises a daily dose of 8 g to ~~15~~ 12 g L-ornithine phenylacetate~~,~~ and provides a plasma Cmax of phenylacetic acid ranging from 10 µg/mL to 150 µg/mL.

~~12. The use of Claim 11, wherein the medicament comprises a daily dose of 8 g to 12 g L-ornithine phenylacetate.~~

~~13.~~10. The use of Claim ~~11 or 12~~9, wherein the plasma Cmax ~~level~~ of phenylacetic acid is from 40 µg/mL to 120 µg/mL.

~~14.~~11. The use of ~~any one of Claims 11 to 13~~Claim 9 or 10, wherein the ~~medicament provides a~~ plasma Cmax of phenylacetylglutamine ~~ranging~~ is from 5 µg/mL to 100 µg/mL.

~~15.~~12. The use of Claim ~~14~~11, wherein the plasma Cmax of phenylacetylglutamine is from 25 µg/mL to 50 µg/mL.

~~16.~~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 the medicament comprises a daily dose of 8 g to ~~15~~ 12 g L-ornithine phenylacetate~~,~~ and provides a plasma $AUC_{0\text{-}t}$ or $AUC_{0\text{-}inf}$ of phenylacetic acid ranging from 100 hr*µg/mL to 1000 hr*µg/mL.

~~17. The use of Claim 16, wherein the medicament comprises a daily dose of 8 g to 12 g L-ornithine phenylacetate.~~

~~18.~~14. The use of Claim ~~16 or 17~~13, wherein the plasma $AUC_{0\text{-}t}$ or $AUC_{0\text{-}inf}$ of phenylacetic acid is from 400 hr*µg/mL to 550 hr*µg/mL.

~~19.~~15. The use of ~~any one of Claims 16 to 18~~Claim 13 or 14, wherein the plasma $AUC_{0\text{-}t}$ or $AUC_{0\text{-}inf}$ of phenylacetylglutamine is from 25 hr*µg/mL to 500 hr*µg/mL.

~~20.~~16. The use of Claim ~~19~~15, wherein the plasma $AUC_{0\text{-}t}$ of phenylacetylglutamine is from 120 hr*µg/mL to 180 hr*µg/mL.

~~21.~~17. The use of Claim ~~19~~15, wherein the plasma $AUC_{0\text{-}inf}$ of phenylacetylglutamine is from 150 hr*µg/mL to 200 hr*µg/mL.

~~22.~~18. The use of any one of Claims ~~7 to 21~~1 to 17, wherein the subject has acute liver failure or chronic liver disease.

~~23.~~19. The use of Claim ~~22~~18, 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.~~20. The use of any one of Claims ~~7 to 21~~1 to 17, wherein the subject has one or more conditions selected from the group consisting of hepatic encephalopathy, portal hypertension, and urea cycle disorder.

~~25.~~21. The use of any one of Claims ~~7 to 24~~1 to 20, wherein the oral pharmaceutical formulation provides an immediate release of L-ornithine phenylacetate.

~~26. The use of any one of Claims 7 to 25, wherein the medicament is for administration once a day.~~

~~27. The use of any one of Claims 7 to 25, wherein the medicament is for administration two or more times a day.~~

~~28. The use of Claim 27, wherein the medicament is for administration two times a day, each time comprising 4 g to 6 g of L-ornithine phenylacetate.~~

~~29. The use of Claim 28, wherein the 4 g to 6 g of L-ornithine phenylacetate is in a single unit dosage form.~~

~~30. The use of Claim 28, wherein the 4 g to 6 g of L-ornithine phenylacetate is in two or more unit dosage forms.~~

~~31. The use of Claim 30, wherein the 4 g to 6 g L-ornithine phenylacetate is in 4 to 6 unit dosage forms each comprising 1 g L-ornithine phenylacetate.~~

~~32.~~22. The use of any one of Claims ~~7 to 31~~1 to 21, wherein said oral pharmaceutical formulation provides conversion of phenylacetate to phenylacetylglutamine of greater than 50% over 24 hours.

~~33.~~23. The use of ~~any one of Claims 7 to 32~~Claim 22, wherein said oral pharmaceutical formulation provides conversion of phenylacetate to phenylacetylglutamine of greater than 80% over 24 hours.

~~34.~~24. The use of any one of Claims ~~7 to 33~~1 to 23, wherein the medicament is for administration with food.