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(54) **DOSING AND MONITORING PATIENTS ON NITROGEN-SCAVENGING DRUGS**

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(57) **ABSTRACT**

The invention provides a method for determining a dose and dosing schedule, and making dose adjustments of patients taking PBA prodrugs as nitrogen scavengers to treat nitrogen retention states, including ammonia accumulation disorders as well as chronic renal failure, by measuring urinary excretion of phenylacetylglutamine and/or total urinary nitrogen. The invention provides methods to select an appropriate dosage of a PBA prodrug based on the patient's dietary protein intake, or based on previous treatments administered to the patient. The methods are applicable to selecting or modifying a dosing regimen for a subject receiving an orally administered waste nitrogen scavenging drug, and to monitoring patients receiving such drugs.

### Human Nitrogen Retention States: Hereditary (UCDs) And Acquired (Cirrhosis) Liver Disease And Chronic Renal Failure (CRF)

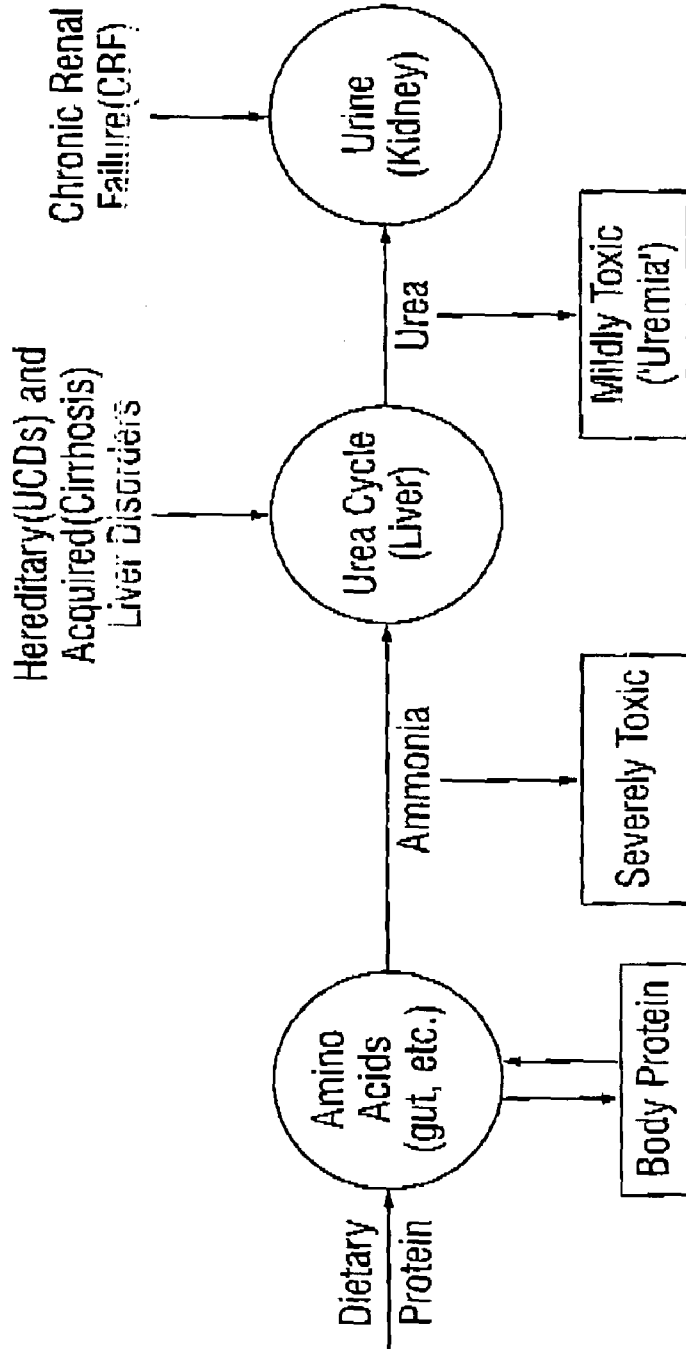


Figure 1a

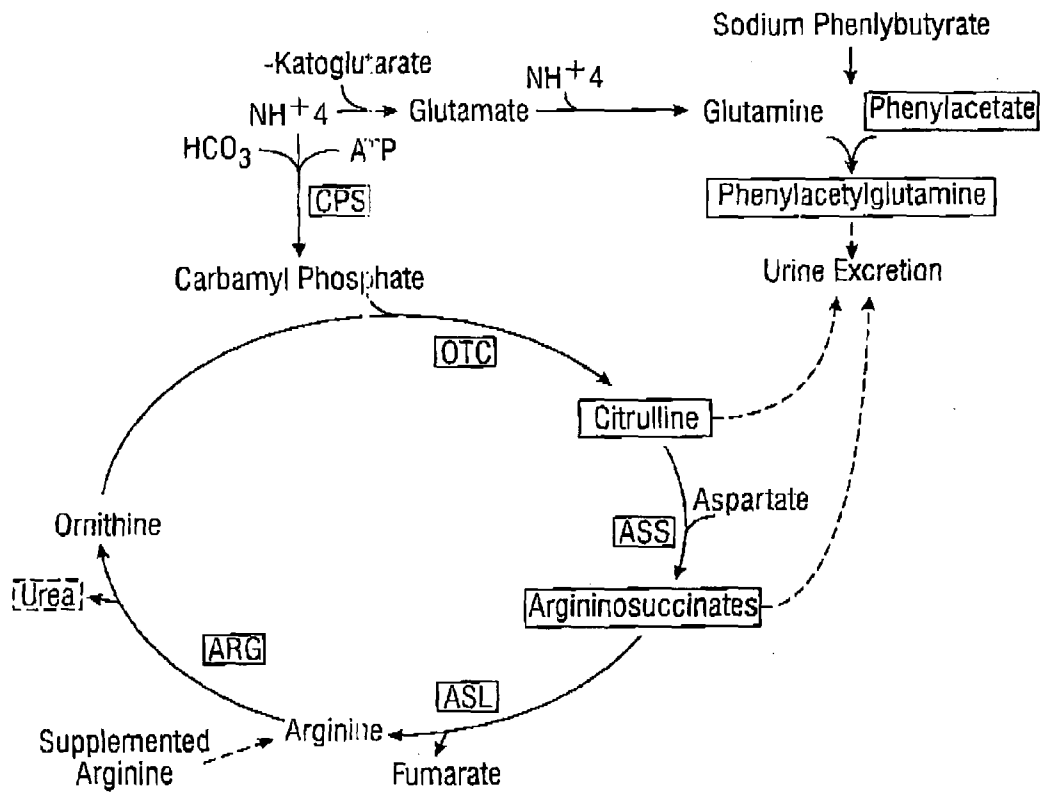
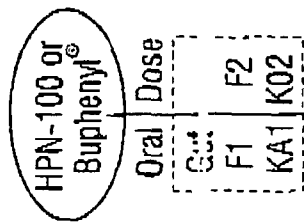


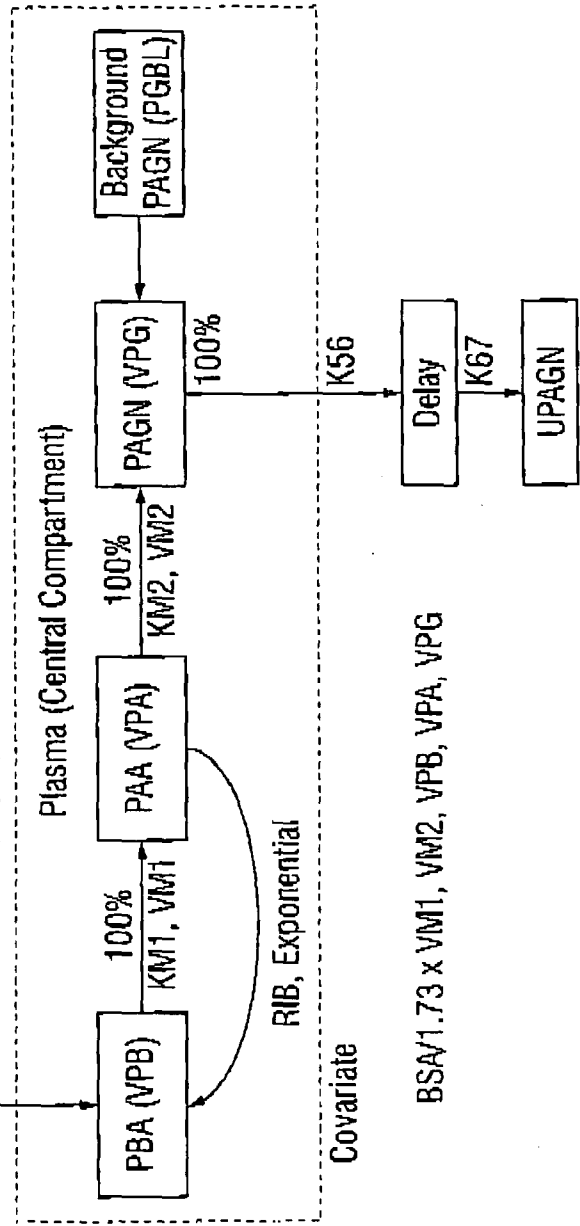
Figure 1b

**PK/PD Modeling of PBA/PAA/PAGN/UPAGN**

- Conventional Approach -



**Note:**  
 This model only allows for conversion of PBA to PAA to PAGN in the systemic (labeled 'central') plasma compartment. Bioavailability and drug effect is assume to relate directly to plasma metabolite concentrations



**Figure 2**

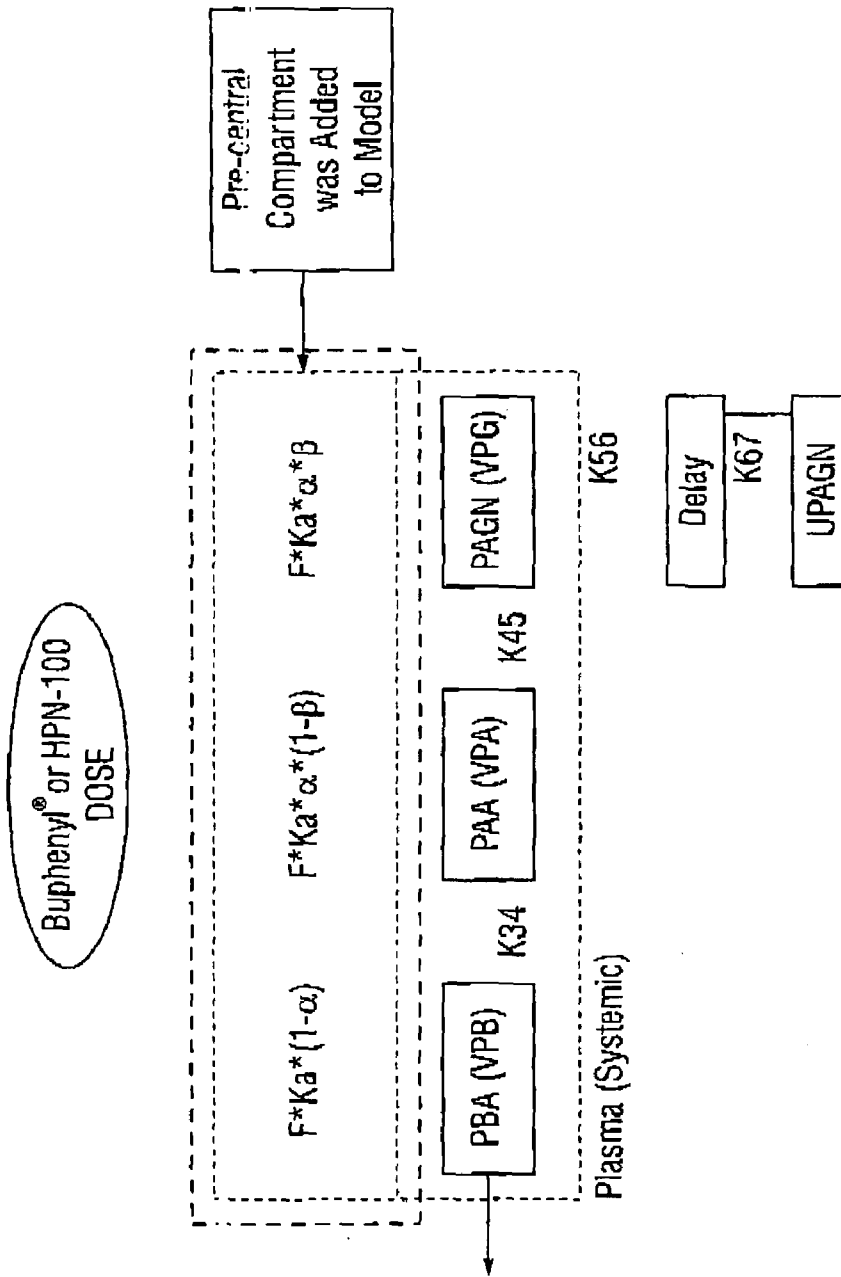


Figure 3

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