

**Important Safety Information for BUPHENYL**

- Any episode of acute hyperammonemia should be treated as a life-threatening emergency.
- BUPHENYL must be combined with dietary protein restriction and, in some cases, essential amino acid supplementation. BUPHENYL should not be administered to patients with known hypersensitivity to sodium phenylbutyrate or any component of this preparation.
- The most common adverse reactions associated with BUPHENYL Tablets were amenorrhea/menstrual dysfunction, decreased appetite, body odor (probably caused by its metabolite, phenylacetate), and bad taste or taste aversion.
- Patients with urea cycle disorders should not take valproic acid, haloperidol, or steroids as these drugs have been reported to increase blood ammonia levels, and probenecid may affect the kidneys' excretion.
- Use with great care, if at all, in patients with congestive heart failure or severe renal insufficiency, and in clinical states where there is sodium retention with edema.
- Use caution when administering to patients with hepatic or renal insufficiency or inborn errors of beta oxidation.
- The safety or efficacy of doses in excess of 20 grams (40 tablets) per day has not been established.