

Important Safety Information for AMMONUL

- **IMPORTANT:** Filtration now required. Due to the possibility that particulate matter may impact the safe use of this product and to ensure optimal patient care, you are instructed to use the *Millex[®] Durapore GV 33 mm Sterile Syringe Filter (0.22 μm)* during the admixture process when injecting AMMONUL into the 10% dextrose IV bag. **Note that particulate matter may not be readily seen on visual inspection, so this filter must be employed in all cases regardless of whether particulate matter is seen in the vial.**
- The most common adverse reactions are vomiting (9%), hyperglycemia (7%), hypokalemia (7%), convulsions (6%), and mental impairments (6%).
- Adverse events occurred most frequently in the following system organ classes: nervous system disorders (22% of patients), metabolism and nutrition disorders (21% of patients), and respiratory, thoracic and mediastinal disorders (15% of patients).
- Do not administer to patients with known hypersensitivity to sodium phenylacetate or sodium benzoate.
- Any episode of acute symptomatic hyperammonemia should be treated as a life-threatening emergency. Uncontrolled hyperammonemia can result in brain damage or death. Dialysis may be required, preferably hemodialysis, to remove a large burden of ammonia.
- Administration must be through a central line; use of a peripheral line may cause burns. Do not administer undiluted product.
- Because of prolonged plasma levels achieved by phenylacetate in pharmacokinetic studies, repeat loading doses should not be administered.
- Use caution when administering to patients with hepatic or renal insufficiency.
- AMMONUL may cause nausea and vomiting. An antiemetic may be administered during infusion.
- Treatment of hyperammonemia also requires caloric supplementation and restriction of dietary protein; intravenous arginine is an essential component of therapy for patients with CPS, OTC, ASS, or ASL deficiency.