



September 15, 2008

Via Overnight Delivery

RE: IMPORTANT SAFETY INFORMATION

Filtration Required for AMMONUL® (sodium phenylacetate and sodium benzoate) Injection 10%/10% (NDC No. 62592-720-50)

Dear Healthcare Professional,

Recently, Ucyclyd Pharma, Inc. (Ucyclyd), a wholly owned subsidiary of Medicis Pharmaceutical Corporation, detected particulate matter in our AMMONUL® (sodium phenylacetate and sodium benzoate) Injection 10%/10% product.

Due to the possibility that this particulate matter may impact the safe use of this product and to ensure optimal patient care, you are being instructed to use a **Millex® Durapore GV 33 mm Sterile Syringe Filter (0.22 µm)** during the admixture process when injecting Ammonul into the 10% Dextrose IV bag. **Please note this particulate matter may not be readily seen on visual inspection, so a filter must be employed in all cases regardless of whether particulate matter is seen in the vial.** Testing has confirmed the removal of this specific particulate when using this filter to admix AMMONUL®.

As a precautionary measure, Ucyclyd will package **Millex® Durapore GV 33 mm Sterile Syringe Filters (0.22 µm)** with all shipments of AMMONUL® until further notice. We apologize for any inconvenience this may have caused.

Ucyclyd shares your commitment to patient safety, and we appreciate your patience and cooperation through this period. To report suspected adverse reactions experienced with the use of this product, and/or quality problems, contact Ucyclyd at 1-800-900-6389 with a representative available 24 hours a day, 7 days a week. These events may also be reported to FDA's MedWatch Program by phone at 1-800-FDA-1088, by fax at 1-800-FDA-0178, by mail at MedWatch, FDA, 5600 Fishers Lane, Rockville, MD, 20852-9787, or on the MedWatch website at www.fda.gov/medwatch.

You may also visit the AMMONUL® website at www.Ammonul.com or FDA's Drug Shortage website at www.fda.gov/cder/drug/shortages/default.htm for additional information.

Sincerely,

Steve Newhard
Senior Vice President, Quality and Technical Services

AMMONUL is a registered trademark of Ucyclyd Pharma, Inc.
Millex is a registered trademark of Millipore Corporation.
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Click the following links for [Safety Information](#) or [Full Prescribing Information](#) on AMMONUL®.