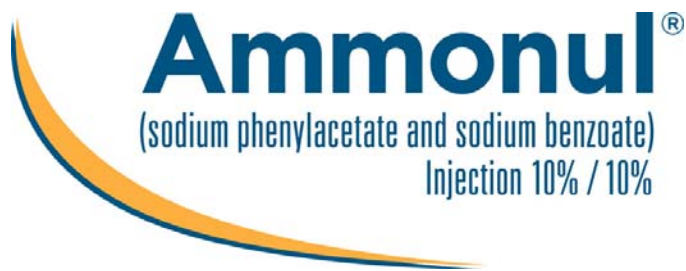


September 18, 2008



## **IMPORTANT: Filtration now required for AMMONUL® Frequently Asked Questions**

Ucyclyd Pharma, Inc. (Ucyclyd) recently detected particulate matter in its 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 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. Please note that this 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.** This filter was chosen because it is made from the same materials as the validated cartridge filters used in the processing of the drug product and it is rated to remove particles 0.22 µm and larger. Testing has confirmed the removal of this specific particulate matter when using this filter to admix AMMONUL®. This filter is widely used in hospitals and pharmacies in the U.S. and Japan and is 510K cleared by the FDA for use in the U.S. market.

Ucyclyd provided *Millex® Durapore GV 33 mm Sterile Syringe Filter (0.22 µm)* to all facilities that received lot 54011P4, which is currently in commercial distribution. As a precautionary measure, future lots of AMMONUL® will be packaged with these filters until further notice.

### **1. Why is filtration necessary?**

Particulate matter was observed in lot 54011P4, which is currently in commercial distribution. Filtration using a 0.22 micron filter is necessary prior to IV admixture to remove any particulate matter that may be present in the vial. Testing has confirmed the removal of this specific particulate matter when using the *Millex® Durapore GV 33 mm Sterile Syringe Filter (0.22 µm)* to admix AMMONUL®. Future lots of AMMONUL® will be packaged with this filter. **Please note that this 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.**

**2. Will filtering this product impact the dosing concentration?**

No.

**3. Am I required to filter during IV admixture?**

Yes.

**4. What filter should I use?**

You should use only the *Millex<sup>®</sup> Durapore GV 33 mm Sterile Syringe Filter (0.22 μm)*, which will be included with future shipments of AMMONUL<sup>®</sup>.

Testing has confirmed the removal of this specific particulate matter when using this filter to admix AMMONUL<sup>®</sup>.

**5. Why is this the only filter I can use?**

The filter material used in *Millex<sup>®</sup> Durapore GV 33 mm Sterile Syringe Filter (0.22 μm)* is the same as what is used during the manufacture of the product. The *Millex<sup>®</sup> Durapore GV 33 mm Sterile Syringe Filter (0.22 μm)* is the only filter for which Ucyglyd has compatibility data to support its use. Additional testing has confirmed the removal of this specific particulate matter when using this filter to admix AMMONUL<sup>®</sup>.

**6. Can I use a filter needle?**

No. The *Millex<sup>®</sup> Durapore GV 33 mm Sterile Syringe Filter (0.22 μm)* is the only filter for which Ucyglyd has compatibility data to support its use. The filter material used in *Millex<sup>®</sup> Durapore GV 33 mm Sterile Syringe Filter (0.22 μm)* is the same as what is used during the manufacture of the product.

**7. Can I just add an in-line filter to the intravenous delivery set-up?**

No, you are being instructed to use the *Millex<sup>®</sup> Durapore GV 33 mm Sterile Syringe Filter (0.22 μm)* during the admixture process when injecting AMMONUL<sup>®</sup> into the 10% dextrose IV bag.

**8. Can I heat the mixture to dissolve the particulate matter?**

No. There is no data to support heating the product.

**9. Has Ucyglyd had any reports of adverse events tied to this particulate matter?**

No adverse events have been reported as of the date of this document. As per standard operating procedure, Ucyglyd continues to monitor any reports of adverse events. To report suspected adverse reactions experienced with the use of this product, and/or quality problems, contact Ucyglyd at 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 800-FDA-1088, by fax at

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](http://www.fda.gov/medwatch).

**10. Can I use the filter for multiple vials?**

No. The *Millex<sup>®</sup> Durapore GV 33 mm Sterile Syringe Filter (0.22 μm)* is for single use only. Ucyclid is providing one filter per vial.

**11. What if I don't have a *Millex<sup>®</sup> Durapore GV 33 mm Sterile Syringe Filter (0.22 μm)* available?**

We suggest you follow your facility procedures and practices to assure patient safety. Ucyclid is providing one filter per vial. Contact Ucyclid at 888-829-2593; we will ship a filter to you overnight at no charge.

**12. Can I be reimbursed if I use my own stock of filters?**

No. Contact Ucyclid at 888-829-2593; we will ship a filter to you overnight.

**13. Where can I find additional information?**

Visit FDA's Drug Shortage website at [www.fda.gov/cder/drug/shortages/default.htm](http://www.fda.gov/cder/drug/shortages/default.htm). Additional information about AMMONUL<sup>®</sup> can be found at [www.Ammonul.com](http://www.Ammonul.com). If you have any further questions, contact us at 800-900-6389, 24 hours a day, 7 days a week.

Click the following links for [Safety Information](#) or [Full Prescribing Information](#) on AMMONUL<sup>®</sup>.