

February 21, 2006

## IMPORTANT PRODUCT INFORMATION

Dear Pharmacist,

This letter is to advise you that Valeant Pharmaceuticals North America has received complaints concerning small cracks at the base of the plastic tip of some Diastat<sup>®</sup> AcuDial (diazepam rectal gel) applicators. Diastat AcuDial is indicated for rectal administration in the management of selected, refractory, patients with epilepsy, on stable regimens of anti-epileptic drugs, who require intermittent use of diazepam to control bouts of increased seizure activity. The product is packaged as twin packs (two syringes in a package), with adjustable dosages set and locked by the pharmacist. Complaints of cracks at the base of the plastic tip have been received for both the 10 mg and 20 mg product twin-packs. We have not received any complaints on the 2.5 mg Diastat (diazepam rectal gel) delivery system.

There is evidence that the product may leak out from these cracks when the plunger is depressed, possibly preventing full dosing and potentially resulting in a sub-optimal therapeutic response. There is also a risk that skin may get pinched on the crack during product insertion and administration. Valeant is working diligently and quickly to resolve this situation. In the interim:

- Visually inspect each applicator for cracks prior to distribution to patients as outlined in the attached instruction sheet.
- Notify Rx Hope at 1-800-511-2120 or [www.Rxhope.com](http://www.Rxhope.com) to return any product with a cracked tip for immediate replacement.
- Patients should bring their Diastat AcuDial with them to the pharmacy for exchange once a replacement is available through the pharmacy.
- Patients should be instructed to keep their current Diastat AcuDial in their possession until a replacement is available through the pharmacy. For any potential seizure emergencies that may arise, immediately dial 911 in the event of a seizure in which the appropriate dose of Diastat delivered cannot be verified with certainty.
- The replacement product will be sent along with a self addressed stamp envelope for exchange of damaged product.
- Advise patients to inspect the Diastat AcuDial applicator as outlined in the attached instruction sheet, and
- Advise patients to return any product with a cracked tip to the pharmacy for replacement as outlined above.
- Patients and pharmacists should also periodically inspect the product for cracks and immediately return and exchange units which have a cracked applicator tip.

As is the case with any patient with epilepsy, emergency support should always be readily available in case seizures are not controllable with Diastat AcuDial. There are no other substitute medications currently available that are FDA approved for at-home therapy to control bouts of increased seizure activity. As stated in the prescribing information, if a decision is made to use Diastat AcuDial, patients should have an emergency number nearby (i.e. 911 or ambulance), to be utilized if appropriate therapeutic response is not achieved. Please refer to Administration Instructions in the complete prescribing information for additional details. Patients and/or caregivers should also have a replacement product available for subsequent use, if clinically appropriate.

Should you have any questions, please contact Medical Information at 1-877-361-2719.

Sincerely,



Dr. Greg Kricorian  
Director, Medical Affairs  
Valeant Pharmaceuticals International

## INSTRUCTION SHEET FOR INSPECTING DIASTAT ACUDIAL

Please follow these 4-step instructions to carefully inspect the Diastat Acudial for any crack. Be careful not to fully remove the cap from the syringe during inspection.



Step 1: Holding syringe in one hand with large end of oval pointing up and down. Place index finger in contact with cap to apply counter force when cap is opened.



Step 2: Using the opposite hand grasp the cap firmly with your index finger, applying pressure to the seal pin to hold it in place.



Step 3: Apply downward force with your thumb to create an opening 2/8 to 3/8" to view base of syringe tip and inspect for crack. Adjust angle to give best view of syringe tip.



Step 4: While maintaining pressure on the seal pin apply an upward force to close the cap. Rotate the syringe 180 degrees and repeat steps 3 and 4.