Information for Healthcare Professionals

Diazepam Rectal Gel
(marketed as Diastat AcuDial)

FDA ALERT [03/2006]: Healthcare professionals, patients with repetitive seizures, and people who care for someone with acute repetitive seizures, should be aware of a manufacturing problem with diazepam rectal gel (Diastat AcuDial) prefilled syringes. There have been over a hundred reports of cracked applicator tips in the 10 and 20 mg rectal syringes. These cracks can let the medicine leak during delivery so that the patient may be under-dosed and not receive enough of the drug to control seizures. Diastat AcuDial syringes should be examined for cracks at the base of the applicator tips before dispensing, and frequently at home. It is important to examine the syringes WITHOUT REMOVING THE CAP, as shown at http://www.diastat.com (click on the "Alert" box to see photos). Any cracked syringes should be taken back to the pharmacy and exchanged for new syringes. In the event of a seizure in which the appropriate dose of Diastat AcuDial delivered cannot be verified with certainty, patients should be told to get emergency medical help immediately by calling 911. The manufacturer is working to correct the problem, but new product will not be available until June or July. Meanwhile, the current stock will remain on the market because there is no other product for home administration for patients with acute repetitive seizures.

This information reflects FDA's current analysis of data available to FDA concerning this drug. FDA intends to update this sheet when additional information or analyses become available.

To report any unexpected adverse or serious events associated with the use of this drug, please contact the FDA MedWatch program using the contact information at the bottom of this sheet.

Considerations

Healthcare professionals should consider the following when prescribing or dispensing Diastat:

- Advise patients or their caregivers to look at their Diastat AcuDial syringes to see if the base of the applicator tip is cracked.
- Advise patients that the CAP SHOULD NOT BE REMOVED during inspection and refer patients to the website (www.diastat.com) or to the Valeant Pharmaceuticals information line at 1-877-361-2719 for specific inspection instructions.
- If any cracks are observed, the syringes should be returned to the pharmacy and exchanged for new syringes.
- Even if no cracks are seen, the syringes should be re-inspected frequently (i.e., monthly) because cracks may appear over time.
- The cracks can result in leakage of the drug product at the time of delivery and under-dosing of patients. If acute repetitive seizures are not adequately treated, the patient may develop status epilepticus, a condition of life-threatening continuous seizures.

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Data Summary

There have been over a hundred reports of cracked applicator tips in DIASTAT ACUDIAL (diazepam rectal gel) DELIVERY SYSTEMS manufactured by Valeant Pharmaceuticals of Costa Mesa, California. The cracks have occurred in both the 10 mg and 20 mg syringes (but not the 2.5 mg syringes).

DIASTAT ACUDIAL DELIVERY SYSTEMS are pre-filled syringes containing diazepam. They are designed to deliver the drug rectally in patients with acute repetitive seizures, a condition that, if inadequately treated, can progress to status epilepticus, a life-threatening condition in which seizures are continuous. The drug is typically administered by family members or caregivers at home.

The frequency of cracks has varied, but as many as 6% of syringes in some lots have shown cracking. The manufacturer has sent letters to pharmacists directing them to inspect the product prior to dispensing, and telling them to inform patients about the need to inspect the syringes (the cracks are easily seen). The manufacturer has also sent letters to physicians who treat patients with epilepsy.

Valeant believes that they have identified the source of the manufacturing problem, but they will not have new product on the market until June or July. Until then, the current product will continue to be sold because there are no other products available that can be administered at home to treat acute repetitive seizures.