



## Patient Information Sheet

### Diazepam Rectal Gel (marketed as Diastat AcuDial)

This is a summary of the most important information about Diastat. For details, talk to your healthcare professional.

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#### FDA ALERT [03/2006]

Cracks have been found in the applicator tips of the 10 and 20 mg Diastat AcuDial prefilled syringes. Medicine can leak through the cracks. If medicine leaks, there may not be enough medicine to treat a seizure.

If you or someone in your care uses Diastat AcuDial, carefully check your pre-filled syringes for cracks. You should check the syringes **WITHOUT REMOVING THE CAP**. For instructions: visit <http://www.diastat.com> and click on the "Alert" Box to see photos, or call Valeant Pharmaceuticals at 1-877-361-2719, about how to check for cracks.

If you see a crack, use a different syringe. Take all cracked syringes back to the pharmacist and exchange them for new syringes. Cracks can appear over time, so keep checking on your syringes to make sure you have good ones ready to use if needed.

If seizures continue after using Diastat, get emergency medical help right away by calling 911.

The company that makes Diastat AcuDial prefilled syringes is working to correct the problem, but new syringes will not be available until June or July. Meanwhile, the old prefilled syringes will still be dispensed because there is no other product available to treat sudden increased 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*

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#### What Is Diastat AcuDial?

Diastat AcuDial is a rectal gel in a prefilled syringe used to stop attacks of sudden increased seizures in patients two years and older who take other seizure medicines regularly, but still have sudden increased seizures.

#### Who Should Not Be Treated With Diastat?

You should not be given Diastat if you have an eye disease called acute narrow angle glaucoma.

#### What Are The Risks?

*The following are the major potential risks and side effects of Diastat therapy. However, this list is not complete.*

- rash
- trouble breathing
- overexcitement
- hallucinating (seeing things or hearing voices that do not exist)
- rage
- impaired judgment, thinking, and motor control (Do not operate a car, bicycle, or dangerous machinery until you have fully recovered from a dose of Diastat.)

**Other side effects** that may occur with Diastat include:

- drowsiness
- dizziness
- headache
- pain
- stomach pain
- nervousness
- flushing
- diarrhea
- feeling unsteady
- abnormal 'high' mood

#### What Should I Tell My Healthcare Professional?

**Before you are given Diastat**, tell your healthcare professional if you:

- have breathing problems
- kidney problems
- liver problems
- drink large amounts of alcohol
- are pregnant, plan to become pregnant, or are breast-feeding

#### Can Other Medicines Or Food Affect Diastat?

Diastat and certain other medicines can interact with each other. Tell your healthcare professional about all the medicines you take including prescription and non-prescription medicines, vitamins, and herbal supplements. Some medicines may affect how Diastat works or Diastat may affect how your other medicines work. Know the medicines you take. Keep a list of them with you to show your healthcare professional.

