

ADMINISTRATION AND DISPOSAL INSTRUCTIONS

Diastat[®]
(diazepam rectal gel)

Diastat[®] AcuDial[™]
(diazepam rectal gel)



IMPORTANT

Read first before using

To the caregiver using DIASTAT:

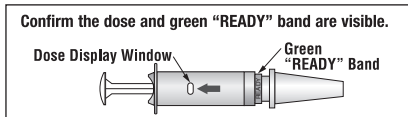
Please do not give DIASTAT until:

1. You have thoroughly read these instructions
2. Reviewed administration steps with the doctor
3. Understand the directions

To the caregiver using DIASTAT ACUDIAL:

Please do not give DIASTAT ACUDIAL until:

1. You have confirmed:
 - Prescribed dose is visible and if known, is correct
 - green "READY" band is visible



2. You have thoroughly read these instructions
3. Reviewed administration steps with the doctor
4. Understand the directions

Please do not administer DIASTAT until you feel comfortable with how to use DIASTAT. The doctor will tell you exactly when to use DIASTAT. When you use DIASTAT correctly and safely you will help bring seizures under control. Be sure to discuss every aspect of your role with the doctor. If you are not comfortable, then discuss your role with the doctor again.

To help the person with seizures:

- ✓ You must be able to tell the difference between cluster and ordinary seizures.
- ✓ You must be comfortable and satisfied that you are able to give DIASTAT.
- ✓ You need to agree with the doctor on the exact conditions when to treat with DIASTAT.
- ✓ You must know how and for how long you should check the person after giving DIASTAT.

To know what responses to expect:

- ✓ You need to know how soon seizures should stop or decrease in frequency after giving DIASTAT.
- ✓ You need to know what you should do if the seizures do not stop or there is a change in the person's breathing, behavior or condition that alarms you.

If you have any questions or feel unsure about using the treatment, **CALL THE DOCTOR** before using DIASTAT.

Where can I find more information and support?

For information on DIASTAT and DIASTAT ACUDIAL:
Call 1-877-361-2719 or
Visit www.diastat.com

Additional resource:

Epilepsy Foundation (EF). You can reach EF by calling 1-800-EFA-1000 or www.efa.org.

When to treat. Based on the doctor's directions or prescription. Your doctor may prescribe a second dose of Diazepam rectal gel. If a second dose is needed, give it 4 hours to 12 hours after the first dose.

Special considerations.

DIASTAT should be used with caution:

- In people with respiratory (breathing) difficulties (such as asthma or pneumonia), kidney or liver disease, or in the elderly
 - In women of child bearing potential, pregnancy and nursing mothers
- Do not use in children under 6 months of age.

Do not use DIASTAT or DIASTAT ACUDIAL together with opioids unless supervised by a health care provider.

Discuss beforehand with the doctor any additional steps you may need to take if there is leakage of DIASTAT or a bowel movement.

Patient's DIASTAT dosage is: _____ mg

Patient's resting breathing rate _____ Patient's current weight _____

Confirm current weight is still the same as when DIASTAT was prescribed _____

Check expiration date and always remove cap before using. Be sure seal pin is removed with the cap.

TREATMENT 1

Important things to tell the doctor.

Date	Seizures Before DIASTAT		
	Time	Seizure Type	No. of Seizures
_____	_____	_____	_____
_____	_____	_____	_____

Time	Seizures After DIASTAT	
	Seizure Type	No. of Seizures
_____	_____	_____
_____	_____	_____

Things to do after treatment with DIASTAT.

Stay with the person for 4 hours and make notes on the following:

- Changes in resting breathing rate _____
- Changes in color _____
- Possible side effects from treatment _____
- Your doctor may prescribe a second dose of Diazepam rectal gel. If a second dose is needed, give it 4 hours to 12 hours after the first dose.

TREATMENT 2

Important things to tell the doctor.

Date	Seizures Before DIASTAT		
	Time	Seizure Type	No. of Seizures
_____	_____	_____	_____
_____	_____	_____	_____

Time	Seizures After DIASTAT	
	Seizure Type	No. of Seizures
_____	_____	_____
_____	_____	_____

Things to do after treatment with DIASTAT.

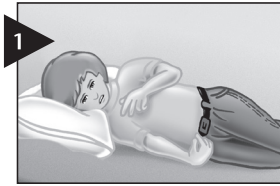
Stay with the person for 4 hours and make notes on the following:

- Changes in resting breathing rate _____
- Changes in color _____
- Possible side effects from treatment _____

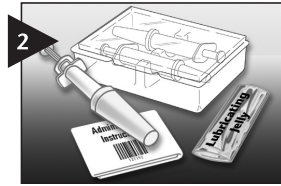
HOW TO ADMINISTER AND DISPOSAL

Diastat[®]
(diazepam rectal gel)

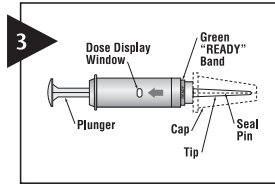
Diastat[®] AcuDial[™]
(diazepam rectal gel)



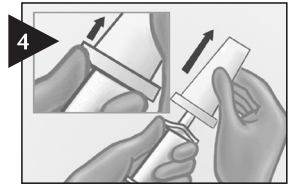
1 Put person on their side where they can't fall.



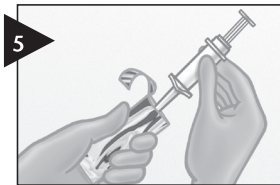
2 Get medicine.



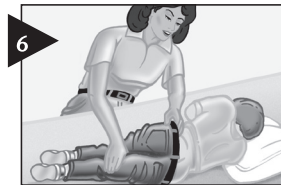
3 Get syringe.
Note: Seal Pin is attached to the cap.



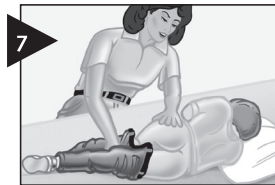
4 Push up with thumb and pull to remove cap from syringe.
Be sure Seal Pin is removed with the cap.



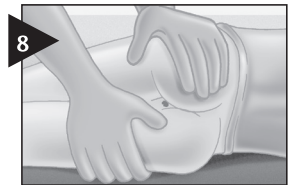
5 Lubricate rectal tip with lubricating jelly.



6 Turn person on side facing you.

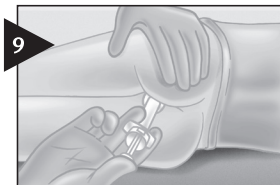


7 Bend upper leg forward to expose rectum.



8 Separate buttocks to expose rectum.

SLOWLY COUNT OUT LOUD TO THREE...1...2...3



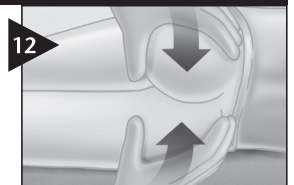
9 Gently insert syringe tip into rectum. *Note: Rim should be snug against rectal opening.*



10 Slowly count to 3 while gently pushing plunger in until it stops.

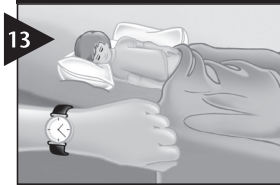


11 Slowly count to 3 before removing syringe from rectum.



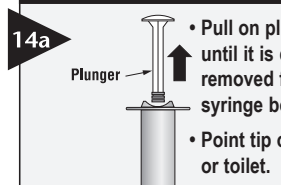
12 Slowly count to 3 while holding buttocks together to prevent leakage.

ONCE DIASTAT IS GIVEN



13 Keep person on side facing you, note time given and continue to observe.

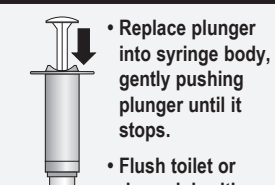
DISPOSAL INSTRUCTIONS FOR DIASTAT ACUDIAL



- Pull on plunger until it is completely removed from the syringe body.
- Point tip over sink or toilet.

This step is for DIASTAT ACUDIAL users only
At the completion of step 14a:

- Discard all used materials in the garbage can.
- Do not reuse.
- Discard in a safe place away from children.



- Replace plunger into syringe body, gently pushing plunger until it stops.
- Flush toilet or rinse sink with water until gel is no longer visible.

DISPOSAL FOR DIASTAT 2.5 MG

- 14b At the completion of step 13:
- Discard all used materials in the garbage can.
 - Do not reuse.
 - Discard in a safe place away from children.



CALL FOR HELP IF ANY OF THE FOLLOWING OCCUR

- Seizure(s) continues 15 minutes after giving DIASTAT or per the doctor's instructions: _____
- Seizure behavior is different from other episodes.
- You are alarmed by the frequency or severity of the seizure(s).
- You are alarmed by the color or breathing of the person.
- The person is having unusual or serious problems.



Local Emergency Number:

_____ (please be sure to note if your area has 911)

Doctor's Number:

Information for Emergency Squad:

Time DIASTAT given: _____

Dose: _____

PLEASE SEE IMPORTANT SAFETY INFORMATION ON PAGE 3.

Please see accompanying full Prescribing Information including Boxed Warning for risks from concomitant use with opioids; abuse, misuse, and addiction; and dependence and withdrawal reactions.

Important Safety Information

DIASTAT® (diazepam rectal gel)

INDICATION

DIASTAT® (diazepam rectal gel) is used to treat occasional episodes of increased seizures that are different from a patient's usual seizure pattern in patients with epilepsy 2 years of age and older.

IMPORTANT SAFETY INFORMATION

- **Potentially fatal effects (trouble breathing and sedation) may occur if DIASTAT is used with opioids. Do not use DIASTAT while you are taking opioids unless you are instructed to do so and are supervised by a health care provider.**
- Do not use DIASTAT if you are allergic to diazepam.
- Do not use DIASTAT if you have an eye condition known as acute narrow angle glaucoma.
- **If you are a caregiver administering DIASTAT, ensure that you have read and understand the Administration and Disposal Instructions section of the DIASTAT full Prescribing Information. Ensure that (1) you can identify the difference between cluster of seizures (and/or the events that precipitate the onset of seizures) from ordinary seizure activity, (2) a doctor confirms that you are able to use the product as instructed, (3) you understand which seizures may or may not be treated with diazepam rectal gel, and (4) you monitor the effect of diazepam rectal gel and know when to seek professional medical help.**
- There is a risk of abuse, misuse, and addiction with DIASTAT, which can lead to overdose and death, especially when used in combination with other medications (e.g., opioid analgesics), alcohol, and/or illicit substances and even at recommended doses. If you experience the signs and symptoms of benzodiazepine abuse, misuse, and/or addiction, including but not limited to delirium, paranoia, suicidal thoughts, seizures, and difficulty breathing, seek medical help. Dispose of unused drug properly, according to the directions from your healthcare provider.
- Do not operate machinery, drive a motor vehicle, or ride a bike until you no longer feel the effects of DIASTAT.
- Do not use DIASTAT with alcohol or in combination with other Central Nervous System (CNS) medications or products that cause respiratory (breathing) or CNS depressant effects. Talk to your doctor if you have any questions about medications or products that you should not use in combination with DIASTAT.
- Prolonged sleepiness has been observed in infants treated with diazepam. Therefore, diazepam rectal gel is not recommended for use in children under six months of age.
- The controlled studies demonstrating the effectiveness of diazepam rectal gel included children two years of age and older. The efficacy and safety of diazepam rectal gel in children under two years of age has not been established.
- No clinical studies have been conducted with diazepam rectal gel in pregnant women. There are concerns about the use of diazepam during pregnancy. Talk to your doctor before using DIASTAT if you are nursing, pregnant, or of childbearing potential.
- Use with caution if you have breathing difficulties (such as asthma or pneumonia), kidney or liver disease, or are elderly. Talk to your doctor if any of these conditions apply to you, or if you are not sure if any of these conditions apply to you.
- Diazepam rectal gel can cause drug addiction. Using DIASTAT more frequently than recommended may lead to physical dependence. Suddenly stopping or reducing the dose of DIASTAT very quickly may precipitate acute withdrawal reactions, which can be life-threatening. In some cases, patients have developed withdrawal symptoms, including but not limited to anxiety, difficulty thinking, mental changes, depression, insomnia, abnormal skin sensations, muscle weakness, tremors, or twitching, ringing in your ears, and a burning or prickling feeling in your hands, arms, or feet, lasting weeks to more than 12 months.
- The most frequent side effect reported for DIASTAT in clinical studies was somnolence (sleepiness or drowsiness). Other side effects included dizziness, headache, pain, abdominal pain, nervousness, vasodilation (increase in diameter of blood vessel), diarrhea, ataxia/incoordination (lack of coordination), euphoria (feeling of great happiness or well-being), asthma, rhinitis (irritation of the nose similar to an allergy or a cold), and rash

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088. You may also contact Bausch Health Customer Service at 1-800-321-4576.

Please see accompanying full Prescribing Information including Boxed Warning for risks from concomitant use with opioids; abuse, misuse, and addiction; and dependence and withdrawal reactions.