

INSTRUCTIONS FOR USE
MIDAZOLAM
 injection, for intramuscular use, CIV
10 mg/0.7 mL Midazolam single-dose autoinjector

Read the Instructions for Use carefully before using the Midazolam autoinjector. A healthcare provider or someone who has adequate training in identifying and treating the symptoms of status epilepticus and first aid/basic airway management should administer the Midazolam autoinjector.

Get medical help right away.

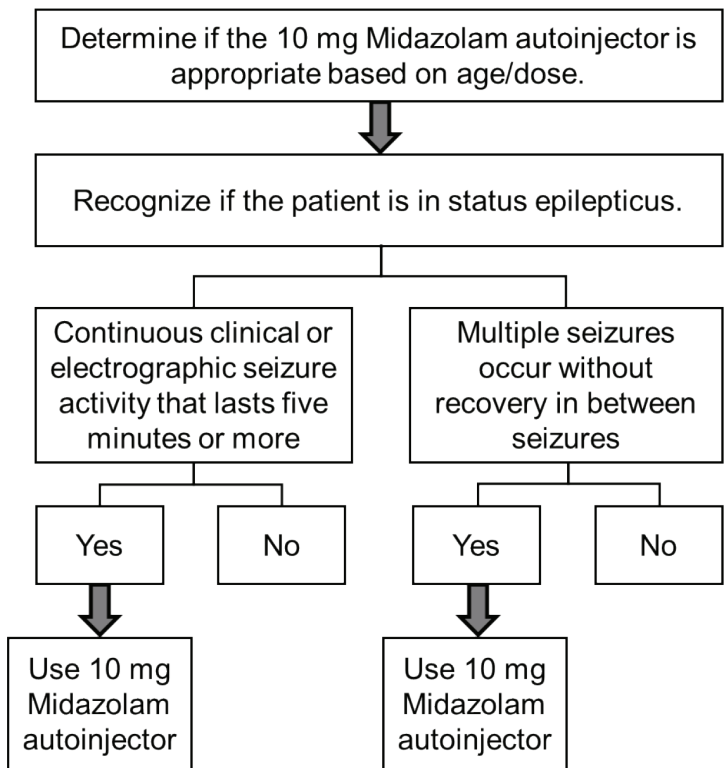
Important Information You Need to Know Before Administering Midazolam:

- Midazolam injection is indicated for the treatment of status epilepticus in adults.
 - Do NOT administer the 10 mg/0.7 mL Midazolam prefilled autoinjector to pediatric patients. Dose adjustment is not possible with the autoinjector.
 - Midazolam injection is not indicated for types of seizures other than status epilepticus (see Figure 1).
- The recommended dose of the Midazolam injection is a single 10 mg dose.
- Each autoinjector is for one-time use only. Do not share or reuse autoinjector.

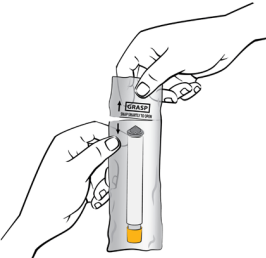
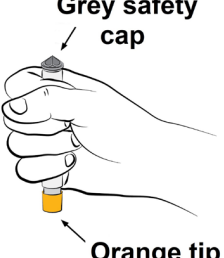

Note: Patients having seizures will likely be unresponsive or may have difficulty in comprehending counseling information.

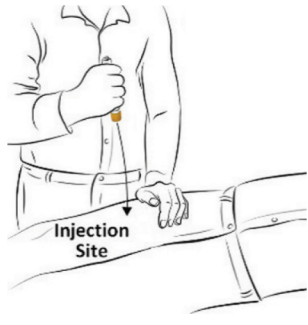

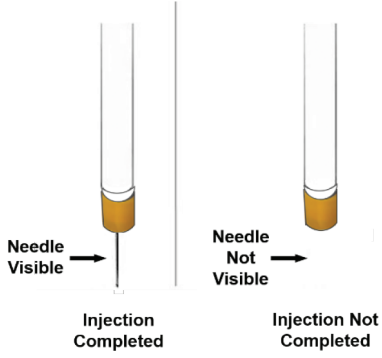
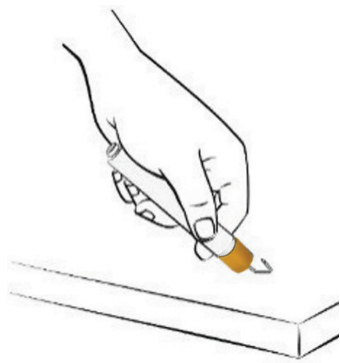
STEP 1: Determine if the Midazolam autoinjector should be administered based on the defined status epilepticus criteria and age of the patient (see Figure 1).

Figure 1: Steps for Determining if Midazolam Autoinjector Should Be Used for Status Epilepticus Treatment



STEP 2: Instructions for How to Use the Midazolam Autoinjector:

	<p>A) Hold the plastic sleeve on both sides of the dotted lines (perforation) and tear apart at the edge to open. Remove the autoinjector from the plastic sleeve. Be careful not to place fingers on the orange tip.</p>
 <p>Grey safety cap Orange tip</p>	<p>B) Firmly hold the autoinjector with the orange tip pointed down.</p>
 <p>Grey safety cap</p>	<p>C) Pull off the grey safety cap with your other hand.</p>

	<p>D) Aim and firmly inject the orange tip straight down (at a 90° angle) against the mid-outer thigh. The autoinjector will give the medicine when you do this. You can inject through clothing, but move all objects from in and around the patient's clothing that may interfere with the injection.</p> <p>Note: For people who do not have a lot of fat at the mid- outer thigh, pinch a fold of skin firmly at the injection site to provide a thicker area for administration.</p>
	<p>E) Hold the autoinjector firmly in place for at least 10 seconds to allow the injection to finish.</p>
	<p>F) After 10 seconds, remove the autoinjector from the outer thigh and massage the injection site in a circle motion for several seconds.</p> <p>Note: If you do not see the needle after removing it from the outer thigh, the injection is not completed. Check to be sure the grey safety cap has been removed. If the grey safety cap has been removed, repeat Step 2 D) to Step 2 E) pressing more firmly against the outer thigh to activate the autoinjector.</p> <p>If you still do not see the needle, use a new autoinjector and start over again at Step 2 A).</p>
	<p>G) After the injection, avoid contact with blood or the needle by carefully bending the needle back against the autoinjector using a hard surface. Use the bent needle as a hook to pin the used autoinjector to the clothing of the person who has been exposed. This will allow medical personnel to see the Midazolam autoinjector was given. You can also put the used autoinjector back into the plastic sleeve and leave it next to the person or write the dose and the autoinjector used on a triage tag, hand, forehead, chest, or other part of the body.</p> <p>Get medical help right away.</p> <p>Each autoinjector has only a single dose (1 injection) of medicine.</p>

STEP 3: Monitoring





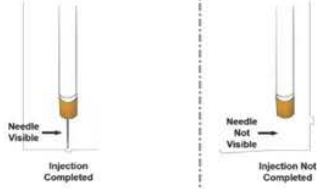
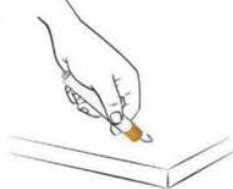
After administration of the Midazolam autoinjector, continuous monitoring of respiratory and cardiac function is recommended until the patient is stabilized.

Patients should be monitored in a setting that allows for immediate access to resuscitative drugs. Appropriate resuscitation equipment and personnel trained in their use and skilled in airway management should be available.

Manufactured and Distributed by:

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Instructions for Use of the Single-Dose		10 mg Midazolam Autoinjector for Buddy-Aid	
<p>1</p>  <p>Grey safety cap Orange tip</p> <p>Open the pouch and hold the autoinjector with the orange tip pointed down.</p>	<p>2</p>  <p>Grey safety cap</p> <p>Pull off the grey safety cap. Do not touch the orange needle end.</p>	<p>3</p>  <p>Injection Site</p> <p>Move all objects from in and around the patient's clothing that may interfere with the injection. Place orange needle end (at a 90° angle) against the mid-outer thigh. Push hard until you feel injector activate. Inject through clothing.</p>	
<p>4</p>  <p>Injection Site</p> <p>Hold firmly in place for 10 seconds to deliver medication. Massage the area for a few seconds.</p>	<p>5</p>  <p>Needle Visible Injection Completed</p> <p>Needle Not Visible Injection Completed</p> <p>If you do not see the needle after removing it from the outer thigh, the injection is not complete. Check to be sure the grey safety cap has been removed, repeat Steps 3-4, pressing more firmly against the outer thigh to activate the autoinjector.</p>		<p>6</p>  <p>After Injection: Bend the needle using a hard surface to form a hook. PUSH the needle of the used injector through a pocket flap of the patient's clothing. Get medical help right away. Verify breathing and pulse.</p>

BACK SIDE
(MIRROR OF FRONT SIDE)

This label may not be the latest approved by FDA.
For current labeling information, please visit <https://www.fda.gov/drugsatfda>



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Gill Sangha

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