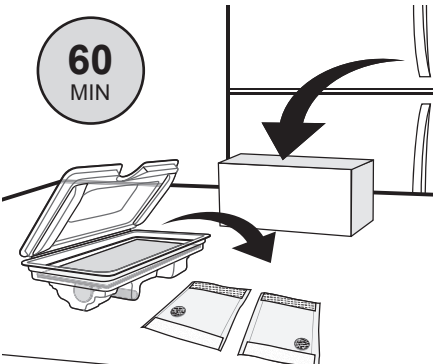
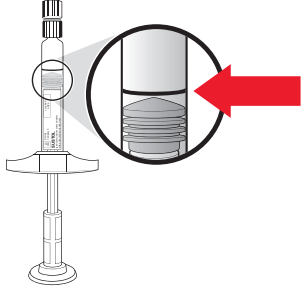
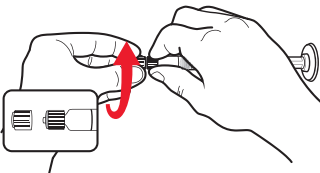
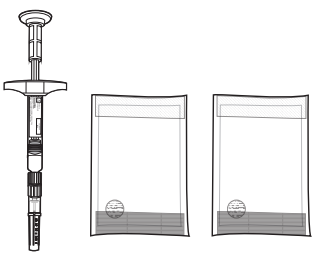
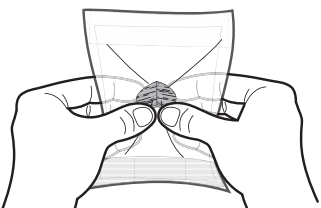


**You must read these complete instructions before you administer SUSTOL for the first time.**

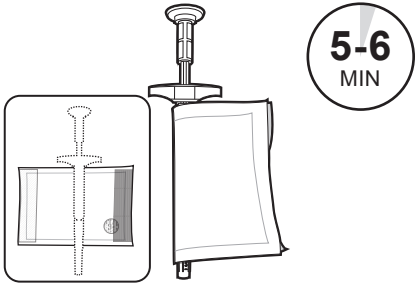
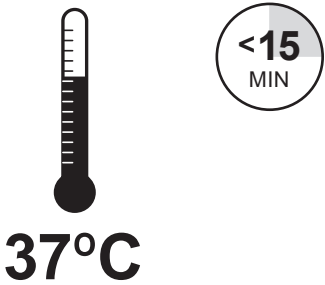
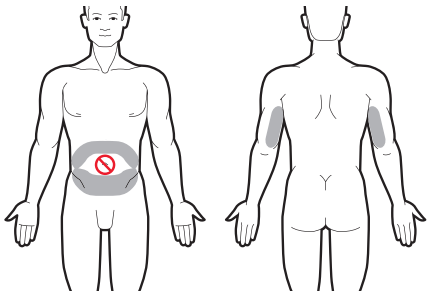
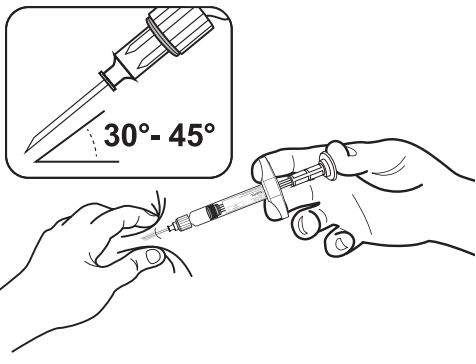
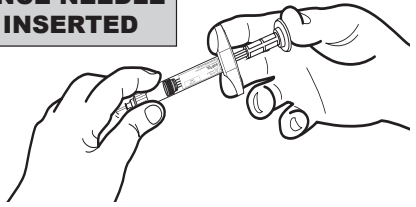
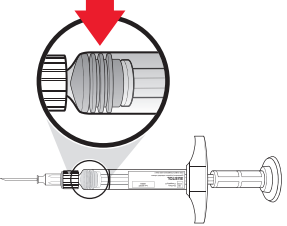
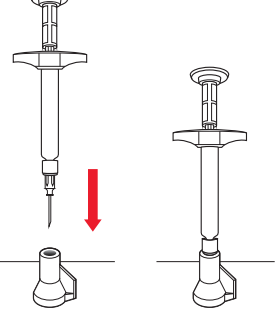
**SUSTOL must be administered by a healthcare provider.**

## Instructions for Use

<p><b>What is SUSTOL?</b></p>	<p>SUSTOL is a subcutaneous injection that provides long-acting antiemetic medication to patients receiving chemotherapy. SUSTOL contains a highly viscous polymer that provides sustained release of granisetron.</p> <p>SUSTOL is supplied as part of an administration kit.</p>	
<p><b>When should you administer SUSTOL?</b></p>	<p>Administer SUSTOL at least 30 minutes before chemotherapy on Day 1 of chemotherapy treatment and not more frequently than once every 7 days, because of the extended-release properties of the formulation.</p>	
<p><b>Before you begin to prepare SUSTOL Injection</b></p>	<p><b>Read these critical instructions.</b></p> <p><i>Do not substitute any of the components from the kit for administration.</i></p> <p>Check to make sure the SUSTOL kit contains:</p> <ul style="list-style-type: none"> <li>• One sterile single-dose glass syringe which contains 10 mg granisetron</li> <li>• One sterile 18G x 5/8" administration needle</li> <li>• Two sodium acetate warming pouches</li> <li>• One Point-Lok<sup>®</sup> needle protection device</li> <li>• Instructions for Use, Package Insert and Medication Guide</li> </ul>	
<p><b>Bring SUSTOL to room temperature</b></p> 	<p><b>STEP</b></p> <p><b>1</b></p>	<p><b>To bring SUSTOL to room temperature:</b></p> <p>Remove SUSTOL kit from refrigeration. Open carton and remove tray. Open tray and unpack warming pouches. Wait a minimum of <b>60 minutes</b> prior to use to allow SUSTOL and the warming pouches to warm to room temperature.</p> <p>SUSTOL may be left out at room temperature overnight, and for up to 7 days, before it must be discarded. SUSTOL may be re-refrigerated if not used within the 7 day period.</p> <p>Warming SUSTOL prior to injection decreases the viscosity and makes administration easier. Bringing SUSTOL to room temperature prior to warming with the sodium acetate warming pouch will facilitate warming of SUSTOL to body temperature.</p>
<p><b>Prepare the syringe</b></p>	<p><b>STEP</b></p>	<p><b>Follow these steps to prepare SUSTOL for use:</b></p>
<p><b>1</b></p>	<p><b>1</b></p>	<p><b>CAUTION</b> Examine all contents of the package. Do not use if any component is damaged.</p>
<p><b>2</b></p>	<p><b>2</b></p>	<p>Check the expiration date on the syringe. Do not use if the expiration date has passed.</p>
<p><b>3</b></p>	<p><b>3</b></p>	<p><b>OPTIONAL</b> Remove the perforated flag label from the plunger rod.</p>
<p><b>4</b></p> 	<p><b>4</b></p>	<p>To ensure that the syringe contains the full dose, check that the gray stopper is close to or below the black line on the syringe barrel label as shown in the illustration.</p> <p>Do <b>NOT</b> expel air bubbles. For a subcutaneous injection, air bubbles in the syringe will not harm the patient.</p>
<p><b>5</b></p> 	<p><b>5</b></p>	<p><b>Unscrew</b> the tip cap from the end of the pre-filled glass syringe.</p> <p>Do <b>NOT</b> use if the tip cap is missing or has been tampered with. Do <b>NOT</b> use if the Luer fitting is missing or dislodged.</p>
<p><b>6</b></p>	<p><b>6</b></p>	<p>Remove the hub cover from the 18G x 5/8" needle supplied with the syringe. Attach the needle to the syringe and seat the needle securely. Do <b>NOT</b> remove the blue needle cover. <b>Do not substitute with any other needle.</b></p> <p><b>CAUTION</b> Use <b>ONLY</b> the 18G x 5/8" needle provided with the syringe because of the highly viscous nature of the medication.</p>
<p><b>Warm SUSTOL to body temperature</b></p>	<p><b>STEP</b></p>	<p><b>Just prior to administering the injection, follow these steps:</b></p>
	<p><b>STEP</b></p>	<p><b>SUSTOL must be warmed to body temperature immediately prior to injection to reduce viscosity and facilitate administration.</b></p> <p>SUSTOL is packaged with two warming pouches. The warming pouches use a non-toxic solution of sodium acetate to create an exothermic (warming) reaction. The second warming pouch can be used if SUSTOL is not immediately administered within the 15 minutes provided by the first warming pouch and needs to be re-warmed.</p> <p>Before activating the warming pouch, make sure that the SUSTOL kit was removed from the refrigerator and that the warming pouches were unpacked from the kit at least 60 minutes prior to use to allow SUSTOL and the warming pouches to warm to room temperature.</p>
	<p><b>1</b></p>	<p>To activate the warming pouch, locate the metal disc and grasp with thumb and forefingers of both hands. Flex (bend) the disc rapidly until crystals begin to form (fluid will start to turn white). Massage warming pouch for a few seconds to soften and to increase the activation rate.</p>

# Instructions for Use

...Continued from front side

	<p><b>2</b> Wrap the SUSTOL syringe and needle in the syringe warming pouch. Use the outline on the warming pouch label as a placement guide for the syringe and needle. Fold the warming pouch over the syringe and press fastening strips together.</p> <p>Allow SUSTOL to warm for 5 - 6 minutes in the warming pouch.</p> <p><b>SUSTOL must be warmed to body temperature immediately prior to injection to reduce viscosity and facilitate administration.</b></p>
	<p><b>3</b> Keep the SUSTOL syringe and needle in the warming pouch until you are ready to administer SUSTOL. The warming pouch will keep the SUSTOL syringe at body temperature for 10 - 15 minutes. If more than 15 minutes has elapsed since warming the SUSTOL syringe, then re-warm the syringe using the second warming pouch prior to injecting SUSTOL.</p> <p><b>CAUTION</b> Sodium acetate is a non-toxic salt. In case of a puncture to a warming pouch and the spilling of the solution or crystals, clean up with soap and water. In case of eye contact, flush with water for 15 minutes. In case of skin contact, wash with soap and water. Seek medical attention if irritation develops or persists.</p> <p>Used warming pouches may be safely disposed of in the trash.</p>
<p><b>Select an injection site</b></p>	<p><b>STEP</b> To select an injection site, use these guidelines:</p>
	<p><b>1</b> Use the <b>skin of the abdomen at least one inch from the umbilicus</b> or the <b>skin of the back of the upper arms</b> as sites for subcutaneous injections.</p> <p><b>WARNING</b> For <b>SUBCUTANEOUS</b> injection only.</p> <p>Do <b>NOT</b> inject within 1 inch of the umbilicus or anywhere the skin is:</p> <ul style="list-style-type: none"> <li>• Burned • Hardened • Inflamed • Swollen • Compromised</li> </ul> <p>For subsequent injections, use the same general area of the body. However, be sure not to inject in the exact same place. Administer new injections at least 1 inch from the previous site.</p>
<p><b>Inject SUSTOL</b></p>	<p><b>STEP</b> Follow these steps to inject SUSTOL:</p>
<p><b>1</b></p>	<p>Remove the syringe from the warming pouch.</p> <p><b>CAUTION</b> The white finger flange on the syringe provides better control when administering SUSTOL. Do <b>NOT</b> remove white finger flange.</p>
	<p><b>2</b> Remove the blue needle cover. Use standard sharps safety techniques to avoid needle sticks.</p> <p><b>3</b> Use standard aseptic technique when performing the injection.</p> <p>Pinch the skin and underlying subcutaneous tissue with your non-dominant hand to create a “tent.”</p> <p>Insert the needle into the subcutaneous tissue at a 30° - 45° angle with your dominant hand.</p> <p><b>WARNING</b> Administer SUSTOL <b>ONLY</b> as a subcutaneous injection. <b>NEVER</b> administer intravenously, intramuscularly or intraperitoneally.</p>
<p><b>OPTIONAL ONCE NEEDLE INSERTED</b></p> 	<p><b>4</b> <b>OPTIONAL</b> For additional stability, once the needle is inserted into the subcutaneous tissue, release the “tent” and hold the syringe barrel with your non-dominant hand.</p>
<p><b>5</b></p>	<p>Press the plunger using a slow, firm, and steady push until you have delivered the entire dose. Do not use excessive force to inject the material more quickly, as this will only result in greater difficulty with the injection.</p> <p><b>CAUTION</b> Due to the high viscosity of SUSTOL, you will experience resistance when injecting SUSTOL. Apply firm and steady pressure to the plunger for about <b>20-30 seconds</b>. Pressing harder will <b>NOT</b> expel SUSTOL faster.</p> <p><b>Do NOT advance or reposition the syringe in the subcutaneous tissue during the injection.</b></p>
	<p><b>6</b> Because SUSTOL is highly viscous, before withdrawing the needle, make sure that the medication is completely expelled by checking the position of the stopper at the base of the syringe barrel.</p>
	<p><b>7</b> Withdraw the needle. Do not remove the needle from the syringe. Use the enclosed Point-Lok® device to prevent needle sticks.</p> <p>Place the Point-Lok needle protection device, supplied within the SUSTOL kit, on a secured flat surface. <b>Do not hold the Point-Lok device in your hand.</b> Carefully insert the exposed needle into the opening at the top of the Point-Lok device and push down until the needle is fully seated in the Point-Lok device. This action will seal the needle tip and lock the needle firmly into the Point-Lok device. Discard the protected needle and attached syringe using your organization’s standard sharps disposal procedures.</p>
<p><b>8</b></p>	<p>Dispense enclosed Medication Guide to each Patient.</p>