



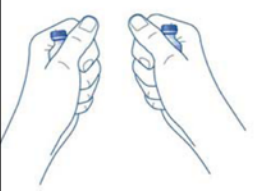

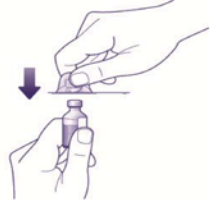
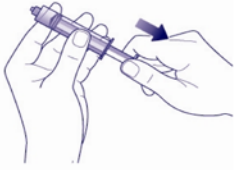
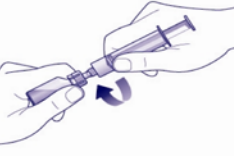
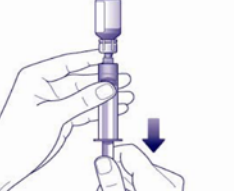





Reconstitution of Tretten®

	<div style="display: flex; justify-content: space-around;"> <div style="text-align: center;"> <p>Water vial</p>  <p>Plastic cap (white) Rubber stopper</p> </div> <div style="text-align: center;"> <p>Powder vial</p>  <p>Plastic cap (orange) Rubber stopper</p> </div> </div> <p>Vial adapter</p>  <p>Protective cap Protective paper Tip Spike</p>	<p>To reconstitute and administer this product you will need the following tools: 10 mL syringe or size of syringe as most convenient according to injection volume, alcohol swabs, the vial adapter included, and an infusion set (tubing, butterfly needle).</p> <p>Reconstitute only with the sterile water for injection (provided with Tretten®).</p> <p>Always use sterile technique.</p>
<p>Step 1</p>		<p>Wash your hands with soap and water before beginning and dry with a clean towel.</p>
<p>Step 2</p>		<p>Bring the powder and solvent vials to room temperature, but not above 25°C. You can do this by holding the vials in your hands.</p>
<p>Step 3</p>		<p>Remove the plastic caps from the two vials. If the caps are loose or missing, do not use the vials. Clean the rubber stoppers on the vials with alcohol swabs and allow them to dry prior to use.</p>
<p>Step 4</p>		<p>The product is reconstituted using the vial adapter included.</p> <p>Remove the protective paper from the vial adapter, without taking the vial adapter out of the protective cap. Attach the vial adapter to the solvent vial (sterile water). Take care not to touch the spike on the vial adapter.</p> <p>Once attached, remove the protective cap from the vial adapter.</p>

<p>Step 5</p>		<p>Pull the plunger to draw in a volume of air that is equal to the amount of solvent in the solvent vial (3.2 mL sterile water).</p>
<p>Step 6</p>		<p>Screw the syringe tightly onto the vial adapter on the solvent vial. Inject air into the vial by pushing the plunger until you feel a clear resistance.</p>
<p>Step 7</p>		<p>Hold the syringe with the solvent vial upside down. Pull the plunger to draw the solvent into the syringe.</p>
<p>Step 8</p>		<p>Remove the empty solvent vial by tipping the syringe with the attached vial adapter.</p>
<p>Step 9</p>		<p>Click the vial adapter, still attached to the syringe onto the powder vial. Hold the syringe slightly tilted with the vial facing downwards. Push the plunger slowly to inject the solvent into the powder vial. Make sure not to aim the stream of solvent directly at the powder as this will cause foaming.</p>
<p>Step 10</p>		<p>Gently swirl the vial until all the powder is dissolved. Do not shake the vial as this will cause foaming. Check the solution for bits and discoloration. If you notice either, do not use it. The reconstituted product is a clear, colourless solution.</p> <p>If you need a larger dose, repeat the procedure in a separate syringe until you have reached your required dose.</p>

Special Additional Instructions for Patients Weighing Less than 24 kg

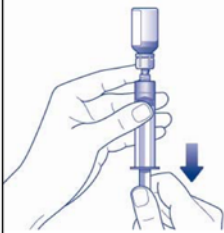
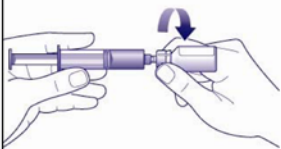

If the body weight is less than 24 kg, the reconstituted **Tretten**® should be further diluted with 6.0 mL of 0.9% sodium chloride. Once further diluted, the dose volume for the reconstituted **Tretten**® is:
Dose volume (mL) diluted **Tretten**® = 0.117 x patient weight (kg).

Your doctor will let you know if this is the case, and provide instruction on how to further dilute **Tretten**®.

Important Information

Once you have prepared **Tretten**® it should be used immediately. This is due to the fact that if left unused, the drug is no longer sterile, and the amount of activate **Tretten**® in the reconstituted vial will increase. Activated **Tretten**® may increase the risk of a blood clot (thrombosis). Product must be used within three (3) hours of reconstitution, and may be left at room temperature after reconstitution until it is used. Any unused product after the 3 hours must be discarded.

GIVING YOUR INJECTION

<p>Step 11</p>		<p>Ensure that the plunger is pushed all the way in before turning the syringe upside down (it may have been pushed out by the pressure in the syringe). Hold the syringe with the vial upside down and pull the plunger to draw up the amount calculated for the injection.</p>
<p>Step 12</p>		<p>Unscrew the vial adapter with the vial. The product is now ready for injection.</p>
<p>Step 13</p>		<p>Infuse as per physician's instructions.</p> <p>Safely dispose of the syringe, vial adapter, infusion set and vials. Any unused product or waste material should be disposed of in accordance with local requirements.</p>

COMMENTS:

Date Effective: 23 Nov 2018

Revised Date: 24 Oct 2018

Version: 1.1

Document#: PTMGNR00056

Approved By: TM Integration Network

For questions or comments, please contact Transfusion.SafetyTeam@ahs.ca