

Warning: Healthcare providers who are immunosuppressed or immunodeficient should not prepare or administer ADSTILADRIN.

STORAGE

Upon receipt, cartons of ADSTILADRIN can be stored as indicated below:



- In a freezer $\leq -60^{\circ}\text{C}$ ($\leq -76^{\circ}\text{F}$) until expiry date printed on the carton
- In a freezer between -25°C to -15°C (-13°F to 5°F) up to 3 months without exceeding the original expiry date printed on the vial and outer carton

ADSTILADRIN can be kept unopened in its shipping container for up to 72 hours from the time it is packaged (noted on the box).

- Once taken out of the freezer or shipping container, the vials may be stored for a maximum of 24 hours at room temperature (20°C to 25°C [68°F to 77°F]) and a maximum of 7 days refrigerated at 2°C to 8°C (36°F to 46°F), including thawing time. Vials can be taken in and out of the refrigerator, provided the maximum duration at each storage temperature is not exceeded. See thaw times below

PREPARATION

- 1. Gather supplies.** In addition to the ADSTILADRIN carton containing **4** vials (each containing 20 mL of clear liquid) in a removable cardboard nest, supplies needed include:



4 sterile vented vial adaptors



2 standard Luer lock adaptors



2 sterile 50- or 60-mL polypropylene syringes



1 sterile straight, or intermittent, urethral catheter with a proximal funnel opening that will accommodate the Luer lock adaptor*



Sterile lubricating jelly



Personal protective equipment per local policy



Biohazard waste container

*Only use catheters made of vinyl/PVC (uncoated or coated with hydrogel), red rubber latex, or silicone to instill ADSTILADRIN. Do NOT use catheters coated or embedded with silver or antibiotics.

- 2. Thaw ADSTILADRIN.** Prior to anticipated administration, thaw the 4 vials of ADSTILADRIN at room temperature (20°C to 25°C [68°F to 77°F]) until they are liquid. Do not expose the vials to higher temperatures; protect from light; and do not refreeze.

THAW TIMES

	Inside nest	Outside nest
At room temperature (up to 25°C [77°F])	8-10 hours	3-5 hours
Time in the refrigerator (up to 8°C [46°F]) [†]	11-13 hours	4-5 hours

[†]To get to room temperature: ~2 hours, 30 minutes outside the nest; 6 hours inside the nest.

- 3. Inspect the ADSTILADRIN vials** to ensure that the product is clear and free of particulates. The suspension should be clear to slightly opalescent and may contain opalescent flecks. If ADSTILADRIN is discolored or contains particles, do NOT use it.
- 4. Place vented vial adaptors on vials using aseptic technique.** Remove the white snap-off cap for each thawed ADSTILADRIN vial. Firmly place 1 vented vial adaptor on each of the 4 vials.
- 5. Attach a syringe onto the vial adaptor, inverting the vial and withdrawing ADSTILADRIN. Draw a total of 75 mL of the medication into 2 sterile syringes.** Make sure any air bubbles are removed before removing the syringe from the vial adaptor. The volumes in the 2 syringes do not have to be equal. After withdrawing the suspension into syringes, the syringes may be stored for up to 6 hours at room temperature (20°C to 25°C [68°F to 77°F]), protected from light.

ADMINISTRATION

- 1. Premedication with an anticholinergic is recommended before each instillation of ADSTILADRIN.**
- 2. Insert catheter and use it to completely empty the patient's bladder** before administration of ADSTILADRIN. Do NOT remove the catheter.
- 3. Attach the Luer lock end of the same catheter adaptor to the syringe containing ADSTILADRIN.**
- 4. Insert the tapered end of the catheter adaptor into the funnel opening of the catheter.**
- 5. Slowly instill 75 mL of ADSTILADRIN into the bladder** through the catheter, ensuring that the complete volume is administered.
- 6. Retain ADSTILADRIN in the bladder for 1 hour after administration.** During the 1-hour dwell time, the patient should be repositioned approximately every 15 minutes from left to right and back to abdomen to maximize bladder surface exposure. If, during dwell time, the patient exhibits bladder cramping or premature voiding, repositioning of the patient may be adjusted or discontinued.

Note: Any urine voided during dwell time should be treated with absorbent material soaked in sodium hypochlorite with 0.5% active chlorine or 6% hydrogen peroxide disinfectant for approximately 15 minutes prior to disposal in biohazard containers per local procedure.
- 7. Evacuate ADSTILADRIN post administration from the bladder** as part of routine emptying of the bladder, or the patient may void and completely empty the bladder after 1 hour has elapsed.

Note: Instruct the patient to void while seated on the toilet after treatment to avoid splashing of urine. For the first 2 days following each instillation of ADSTILADRIN, patients and caregivers should be instructed to add half a cup (~4 oz) of bleach to the toilet bowl prior to voiding, and wait 15 minutes before flushing the toilet.

DISPOSAL

Note: There will be 5 mL of ADSTILADRIN remaining in 1 vial after removing the 75 mL required. Dispose of unused product and disposable materials that may have come into contact with ADSTILADRIN in accordance with local biosafety guidelines applicable for handling and disposal of biohazard waste.

- Spills of ADSTILADRIN should be treated with a virucidal agent for 15 minutes
- Disposable materials that have come into contact with ADSTILADRIN should be placed in biohazard containers for destruction
- Nondisposable equipment should be decontaminated by autoclaving or sterilizing with appropriate disinfectant or virucidal agent, or according to the facility's standard operating procedures

Please see full [Prescribing Information](#).



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