VALSTAR®
(valrubicin) 200 mg/5 mL Sterile Solution for Intravesical Instillation

Preparation and Administration Guide

Each VALSTAR® shipment includes

VALSTAR® Sterile Solution for Intravesical Instillation

- 1 carton of four, 5-mL single-use vials (200 mg/5 mL).
  - — Store vials under refrigeration at 2°-8°C (36°-46°F) in the carton. Do not freeze.
  - — Unopened vials of VALSTAR are stable until the date indicated on the package when stored under refrigerated conditions at 2°-8°C (36°-46°F).

Intravesical Chemotherapy Administration Kit

- 1 each—Administration Tubing with Decanting Spike.
- 1 each—PAB®* Instillation Container with 100 mL of 0.9% Sodium Chloride, USP (Sterile, preservative-free), Diluent.

*PAB® (Partial Additive Bag) is a registered trademark of B. Braun Medical Inc. PAB is Latex-free, DEHP-free, and PVC-free.

Additional supplies needed (not included)

- 2 sterile, disposable syringes, needles, catheter, and alcohol wipes.
  - — The use of goggles, gloves, and a protective gown is recommended during preparation and administration of VALSTAR.

VALSTAR is recommended at a dose of 800 mg administered intravesically once a week for 6 weeks. For additional information, please refer to the Dosage and Administration section of the Prescribing Information for VALSTAR.

Please see full Prescribing Information for VALSTAR at www.ValstarSolution.com

Preparation

1. For each instillation, 4 VALSTAR® 5-mL vials (containing 200 mg valrubicin solution) should be allowed to warm slowly to room temperature but should not be heated. For example, this may take 20 to 30 minutes.
   - *Use of goggles, gloves, and protective gowns is recommended during preparation and administration of the drug.*

2. Prepare the VALSTAR solution using the PAB® Instillation Container with 0.9% Sodium Chloride Injection (supplied) for administration according to the label instructions.

3. Remove the blue tab from the instillation container and, using a disposable sterile syringe and needle (not provided), remove 45 mL of the 0.9% sodium chloride solution from the instillation container and discard. This will leave 55 mL of the sodium chloride solution in the instillation container before adding VALSTAR.

4. Using another disposable sterile syringe and needle (not provided), draw up 5 mL (entire volume) of the VALSTAR solution from the vial (red solution) and inject into the instillation container. Repeat this procedure for each of the remaining 3 VALSTAR vials for a total of 20 mL of VALSTAR solution.
   - *Remember, when preparing* VALSTAR, *do not inject air into the* VALSTAR *vials.*

5. Now you will have a final instillation volume of 75 mL (55 mL of 0.9% Sodium Chloride, plus 20 mL of VALSTAR solution).

6. Gently shake the instillation container until an even mixture is obtained. Inspect the solution prior to administration. Dispose of any solution that contains particulate matter or is discolored. (VALSTAR Sterile Solution is a clear red solution.)
   - VALSTAR *diluted in 0.9% Sodium Chloride Injection for administration is stable for 12 hours at temperatures up to 25°C (77°F).*

Please see full Prescribing Information for VALSTAR at www.ValstarSolution.com

Administration

VALSTAR® should be administered under the supervision of a physician experienced in the use of intravesical chemotherapeutic agents.

1. Remove the white cap from the PAB® Instillation Container and carefully insert the decanting spike into the instillation container, using caution not to exert excessive force or puncture the container. Ensure that the tubing is clamped.

2. Hang the instillation container of VALSTAR solution from an IV pole or hold it above the patient by hand. Squeeze the priming chamber at the base of the decanting spike; unclamp the tubing, prime with VALSTAR solution, and reclamp.

3. Remove the cap from the distal end of the tubing and insert it into the patient's indwelling catheter.

4. Unclamp the tubing and slowly instill diluted VALSTAR intravesically by gravity flow over a period of several minutes.

5. Withdraw the catheter. The patient should be instructed to retain the VALSTAR solution for 2 hours. At the end of 2 hours, the patient should void.

Administration Precautions

- When handling and disposing of VALSTAR, appropriate procedures for proper handling and disposal of anticancer drugs should be used. Remember to consult your institutional or practice guidelines and recommendations.
- Any solution that leaks out of the bladder and onto the patient should be cleaned up immediately with soap and water.
- VALSTAR will stain surfaces. Spills should be cleaned up with undiluted chlorine bleach.
- The use of goggles, gloves, and protective gowns is recommended during preparation and administration of VALSTAR.
- Use aseptic technique during preparation and administration.
- VALSTAR should be administered under the supervision of a physician experienced in the use of intravesical chemotherapeutic agents.

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Please see additional Administration Precautions on the last page.

Administration Precautions (continued)

- As recommended with other cytotoxic agents, caution should be exercised in handling and preparing the solution of VALSTAR®.
- Contact toxicity, common and severe with other anthracyclines, is not typical with VALSTAR and, when observed, has been mild. Skin reactions may occur with accidental exposure.
- The personnel preparing the PAB® Instillation Container should review and be familiar with the current VALSTAR Prescribing Information, including the Dosage and Administration section.
- If the eye is accidentally exposed to VALSTAR, the eye should be flushed thoroughly with water immediately.
- Administration should be delayed at least 2 weeks after transurethral resection and/or fulguration.
- Healthcare professionals (HCPs) should report adverse events, product concerns, or complaints, and make requests for medical and/or technical information concerning Endo products by calling 1-800-462-ENDO (3636).

Indication

VALSTAR® (valrubicin) is indicated for intravesical therapy of BCG-refractory carcinoma *in situ* (CIS) of the urinary bladder in patients for whom immediate cystectomy would be associated with unacceptable morbidity or mortality.

Important Safety Information

- VALSTAR is contraindicated in patients with known hypersensitivity to anthracyclines or polyoxyl castor oil. VALSTAR should not be administered to patients with a perforated bladder, compromised bladder mucosa integrity, concurrent urinary tract infections, or small bladder capacity (unable to tolerate a 75 mL instillation). The integrity of the bladder should be confirmed prior to instillation of VALSTAR in those patients who have had procedures with the potential to compromise the bladder wall.
- Patients should be informed that VALSTAR has been shown to induce complete response in about 1 in 5 patients with BCG-refractory CIS. Delaying cystectomy could lead to development of metastatic bladder cancer. **If there is not a complete response of CIS to treatment after 3 months or if CIS recurs, cystectomy must be reconsidered.**
- VALSTAR should be administered using aseptic technique under the supervision of a practitioner experienced in the use of intravesical cancer chemotherapeutic agents. VALSTAR should be used with caution in patients with severe irritable bladder symptoms. Patients of reproductive age should be advised to use an effective contraception method. Myelosuppression is possible if VALSTAR is inadvertently administered systemically or if significant systemic exposure occurs following intravesical administration (e.g., in patients with bladder rupture/perforation). If VALSTAR is administered when bladder rupture or perforation is suspected, weekly monitoring of complete blood counts should be performed for 3 weeks.
- In clinical trials, the most common local adverse events include urinary frequency, urinary urgency and dysuria. The most common systemic adverse events include urinary tract infection, abdominal pain, nausea, asthenia, headache, malaise and urinary retention.
- Patients receiving VALSTAR must be closely monitored for disease recurrence or progression. The recommended evaluation should include cystoscopy, biopsy, and/or urine cytology every 3 months.

Please see full Prescribing Information for VALSTAR at www.ValstarSolution.com

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endo Pharmaceuticals

Rx Only

VL-00769e(1)/March 2014 www.valstarsolution.com 1-800-462-ENDO (3636)