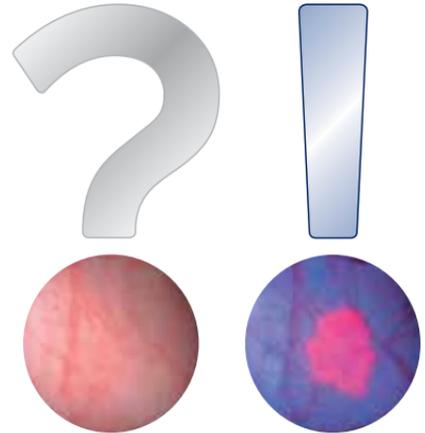




SEE WHAT YOU HAVE BEEN MISSING IN BLADDER CANCER

A Health Care Professional's Guide

- Reconstitution of Cysview
- Instillation of Cysview
- Checklist for Blue Light Cystoscopy with Cysview



Cysview (hexaminolevulinate hydrochloride) for Intravesical Solution

Product Indication:

Cysview is an optical imaging agent indicated for use in the cystoscopic detection of non-muscle invasive papillary cancer of the bladder among patients suspected or known to have lesion(s) on the basis of a prior cystoscopy. Cysview is used with the Karl Storz D-Light C Photodynamic Diagnostic (PDD) system to perform cystoscopy with the blue light setting (Mode 2) as an adjunct to the white light setting (Mode 1).

Cysview is not for repetitive use and is not a replacement for random bladder biopsies or other procedures used in the detection of bladder cancer.



Equipment you need to reconstitute Cysview

1 vial Cysview	Alcohol prep pads
1 vial DILUENT for Cysview	Sterile syringe cap
1 Luer Lock catheter adapter	Gloves
Sterile 50 mL Luer Lock syringe	Safety needle
Sterile urinary catheterization kit	Sharps container



Reconstitution of Cysview

Cysview is supplied as a kit containing two vials: a clear glass vial labeled as Cysview (hexaminolevulinate hydrochloride) for Intravesical Solution, containing 100 mg hexaminolevulinate hydrochloride as a powder, and a vial labeled as DILUENT for Cysview, containing 50 mL of the diluent in a polypropylene vial.

Perform all steps under aseptic conditions. Use gloves during the reconstitution procedure; skin exposure to hexaminolevulinate hydrochloride may increase the risk for sensitization to the drug.

Use a 50 mL syringe with a Luer Lock tip throughout the reconstitution procedure to ensure that the correct concentration (2 mg/mL) of the drug is obtained and that a stable syringe-catheter connection is made for the bladder instillation of Cysview.



1

Remove the cap from the sterile 50 mL syringe and carefully retain it for subsequent reattachment to the syringe (step 4). Attach a needle to the syringe and withdraw 50 mL of the diluent.





2

Penetrate the stopper of the Cysview powder vial with the needle and inject 10 mL of the diluent from the syringe into the powder vial.



3

Without withdrawing the needle from the vial, hold the powder vial and syringe in a firm grip and gently shake to dissolve of the powder in the diluent. The powder normally dissolves almost immediately.



4

Withdraw all of the dissolved solution from the powder vial (10 mL) into the 50 mL syringe.



Reconstitution of Cysview

5

Remove the needle from the powder vial, disconnect the needle from the syringe tip and discard it. Plug the syringe with the syringe cap. Gently mix the contents of the syringe. The reconstituted solution of Cysview is colorless to pale yellow and clear to slightly opalescent, and free from visible particles.



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Peel off the detachable portion of the label (starting at the corner marked with a black triangle) from the Cysview powder vial and affix it to the syringe containing the solution of Cysview. Add two hours to the present time and write the resulting expiration time and date on the syringe label.

Cysview is now reconstituted and ready for use. Instill the reconstituted solution of Cysview into the bladder. If unable to administer the solution shortly after reconstitution, the solution may be stored for up to 2 hours in a refrigerator at 2°-8°C (36°- 46°F) in the labeled syringe. If not used within 2 hours, discard the solution.



Bladder Instillation of Cysview

For bladder instillation of the solution of Cysview, use straight, or intermittent, urethral catheters with a proximal funnel opening that will accommodate the Luer Lock adapter. Use only catheters made of vinyl (uncoated or coated with hydrogel), latex (amber or red), and silicone to instill the reconstituted Cysview. Do not use catheters coated or embedded with silver or antibiotics. In-dwelling bladder catheters (Foley catheters) may be used if the catheters are inserted shortly prior to Cysview administration and are removed following the Cysview instillation.

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1. Using standard sterile catheterization technique, first insert the urethral catheter into the bladder of the patient and use the catheter to completely empty the patient's bladder before instillation of Cysview.
2. To attach the syringe containing the solution of Cysview to the catheter, do the following:
 - Remove the syringe cap from the 50 mL syringe that contains the solution of Cysview.
 - Attach the Luer Lock end of the (provided) catheter adapter to the syringe.
 - Insert the tapered end of the catheter adapter into the funnel opening of the catheter.
3. Slowly instill the solution of Cysview into the bladder through the catheter, ensuring that the complete volume of the syringe (50 mL) is administered.
4. After the solution is instilled, remove the catheter and instruct the patient to retain the solution within the bladder for at least 1 hour; do not exceed 3 hours [see Dosage and Administration (2.4)]. Patients may stand, sit and move about during the time period between instillation and start of the cystoscopic procedure.
5. Evacuate the solution of Cysview from the bladder as part of routine emptying of the bladder immediately prior to the initiation of the cystoscopic procedure (refer to the Karl Storz PDD Telescope Instruction manual). Also, the patient may void and completely empty the bladder prior to the procedure. Avoid skin contact with Cysview. If skin does come in contact with Cysview, wash immediately with soap and water and dry off. After voiding the bladder of Cysview, routinely wash the patient's perineal skin region with soap and water and dry.

Blue Light Cystoscopy with Cysview Checklist

Timing the cystoscopic examination

- ✓ Initiate the cystoscopic examination within 30 minutes after evacuation of Cysview from the bladder, but no less than one or more than three hours after Cysview is instilled in the bladder. If the patient did not retain Cysview in the bladder for one hour, allow one hour to pass from the instillation of Cysview into the bladder to the start of the cystoscopic examination.

system
setup



Light source settings

Is the correct light source and setting for Cysview cystoscopy being used?

- ✓ Check that the correct model number of light source is used and the correct light mode is selected. It should be Karl Storz D-light C light source with “PDD” appearing on the light source display when in fluorescence cystoscopy mode.
- ⓘ The Xenon bulb should be checked, as useful lifetime is typically 300-400 hours.

light source





Light cable

- ✓ Only fluid light cables of small diameter (2-3mm) are suitable for use for fluorescence cystoscopy. These cannot be sterilized by autoclaving.
- ⓘ *If there is insufficient light intensity seen during fluorescence cystoscopy, a defective fluid light cable could be the cause, or the connection between the light source and cable may be incorrect.*



light cable

Camera

Is the correct PDD Camera being used for fluorescence cystoscopy?

- ✓ In addition, the camera also should be connected to the light source via a light-control cable, which ensures that both the light source and camera are in blue or white light mode at the same time.
- ✓ Refer to the manufacturer's instructions to prepare the settings for camera head and/or foot pedal switches.
- ⓘ *If the correct camera is not used the bladder could appear very dark.*



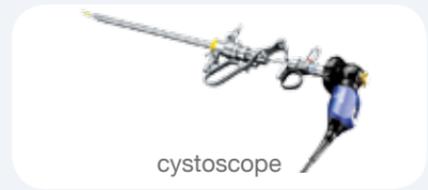
camera system

Blue Light Cystoscopy with Cysview Checklist

Telescope

Is the correct PDD cystoscopy telescope being used?

- ✓ These are usually marked with a colored ring near the eyepiece (violet/blue). The model number should be 27005AIA, BIA, or CIA.
- ✓ They contain a filter so a white object will appear slightly yellowish when viewed through the telescope.
- ❗ *If the correct telescope is not used the bladder could appear very dark or uniformly bright blue.*



Monitor

- ✓ Check that the monitor is connected correctly (particularly if routed through a video or other recording device) and that its settings are neutral.

Bladder examination

- ✓ When examining the bladder using the blue light cystoscopy mode, the bladder neck should show pinkish/red fluorescence, indicating that Cysview instillation was successful.
- ❗ *If the bladder appears uniformly pink/red, widespread inflammation due to infection or very recent intravesical therapy could be the cause.*
- ✓ Urine will show as green under blue light conditions and could interfere with the examination.
- ✓ Tangential light may give false fluorescence. To help avoid false fluorescence, hold the endoscope perpendicular and close to the bladder wall with the bladder distended.

Training and proficiency in cystoscopic procedures are essential prior to the use of Cysview. Carefully review the instruction manuals provided with the Karl Storz D-Light Photodynamic Diagnosis (PDD) System.



OPTIMAL PATIENT PROFILES FOR BLUE LIGHT CYSTOSCOPY WITH CYSVIEW®



Patients who may benefit from Blue Light Cystoscopy with Cysview

- Cysview is indicated for use among patients suspected or known to have lesion(s) on the basis of a prior cystoscopy¹
- Based on extensive long-term clinical experience, a European expert panel recommended that the following patient types may be considered as candidates for use with Cysview PDD^{2,3}:
 - all patients on initial suspicion of bladder cancer at primary cystoscopy and resection of bladder tumors
 - all patients not previously evaluated with Cysview PDD for assessment at time of tumor recurrence
 - patients with multiple Ta/T1 papillary tumors
 - patients with positive urine cytology and negative white-light cystoscopy

Contraindications for Blue Light Cystoscopy with Cysview

Do not use Cysview in patients with¹:

- porphyria
- gross hematuria
- BCG immunotherapy or intravesical chemotherapy within the past 90 days
- known hypersensitivity to hexaminolevulinat or aminolevulinat derivatives

Important Risk and Safety Information about Cysview

Cysview is not a replacement for random bladder biopsies or other procedures used in the detection of bladder cancer and is not for repetitive use.

Anaphylaxis reactions including anaphylactoid shock, hypersensitivity reactions, bladder pain, cystitis, and abnormal urinalysis have been reported after administration of Cysview. The most common adverse reactions seen in clinical trials were bladder spasm, dysuria, hematuria, and bladder pain.

Cysview should not be used in patients with porphyria, gross hematuria, or with known hypersensitivity to hexaminolevulinate, or in patients receiving intravesical chemotherapy or BCG treatment within 3 months of Cysview photodynamic blue-light cystoscopy. There are no known drug interactions with hexaminolevulinate; however, no specific drug interaction studies have been performed. Using Cysview, fluorescence of non-malignant areas may occur, and Cysview may fail to detect some malignant lesions.

Cysview must be used with the Karl Storz D-Light C Photodynamic Diagnostic (PDD) system. For system set up and general information for the safe use of the PDD system, please refer to the Karl Storz instruction manuals for each of the components.

Contact Photocure Inc:
Telephone: 1-855-CYSVIEW
(1-855-297-8439)

www.cysview.com

For additional training in the use of the PDD System, contact:
Technical Support of Karl Storz Endoscopy-America, Inc.,
Telephone: 800-421-0837, Ext. 5350.

Reference: 1. Cysview Prescribing Information
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