

For non-muscle invasive bladder cancer
Blue Light Cystoscopy with Cysview®

Reconstitution and Instillation of Cysview®



A Healthcare Professionals' Guide

CYSVIEW®
Hexaminolevulinate HCl

Blue Light Cystoscopy with Cysview

Equipment you need to reconstitute Cysview®

Handling instructions for the pharmacist and other healthcare professionals:

All steps should be performed with sterile equipment and under aseptic conditions. Wear gloves during the reconstitution procedure; skin exposure to hexaminolevulinate hydrochloride may increase the risk for sensitization to the drug.

Cysview kit, which includes:

- One 100 mg vial of Cysview powder (hexaminolevulinate HCl)
- One vial adapter
- One syringe plunger
- One Luer Lock catheter adapter
- One prefilled syringe containing 50 mL diluent for Cysview

Other materials needed

- Sterile urinary catheterization kit
- Alcohol prep pads
- Gloves



Cysview Indication

Cysview is an optical imaging agent indicated for use in the cystoscopic detection of carcinoma of the bladder, including carcinoma in situ (CIS), among patients suspected or known to have lesion(s) on the basis of a prior cystoscopy, or in patients undergoing surveillance cystoscopy for carcinoma of the bladder. Cysview is used with the KARL STORZ D-Light C Photodynamic Diagnostic (PDD) system to perform Blue Light Cystoscopy (BLC®) as an adjunct to White Light Cystoscopy. Cysview is not a replacement for random bladder biopsies or other procedures used in the detection of bladder cancer.¹

Reference: 1. Cysview [prescribing information]. 2019:1-4.

Cysview® Reconstitution: Using a vial adapter



1

Fasten the plunger rod into the rubber stopper of the pre-filled syringe by turning the plunger rod clockwise until it stops.

2

Remove the plastic cap from the vial. Remove the Tyvek® cover from the vial adapter blister package.

Do not remove the vial adapter from the package.

Place the Cysview powder vial on a flat surface.

Using the blister package to hold the vial adapter, **connect to the vial with a downward vertical motion.**

The vial adapter snaps onto the vial as the spike penetrates the rubber stopper of the vial.

Remove the plastic blister package and discard it. Take care not to touch the exposed end of the vial adapter.



For more details, please see the Full Prescribing Information in pocket.

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Cysview® Reconstitution: Prepare the syringe



- 3** **Remove the cap from the pre-filled syringe** and carefully retain it for subsequent reattachment to the syringe.
- Hold the pre-filled syringe upright and carefully press the plunger rod upward to remove air. Connect the syringe to the vial adapter.
- Inject about 10 mL of the diluent** from the pre-filled syringe down into the powder vial. The vial should be about $\frac{3}{4}$ full.



- 4** Without disconnecting the vial adapter from the vial, **hold the powder vial and syringe in a firm grip and gently shake** to dissolve the powder in the diluent.
- The powder normally dissolves almost immediately.

For more details, please see the Full Prescribing Information in pocket.



- 5** Turn the vial upside down and **withdraw all of the dissolved solution** from the powder vial back into the syringe.



- 6** **Disconnect the empty vial with the vial adapter** from the syringe tip and discard them. Plug the syringe with the syringe cap. Gently mix the contents of the syringe.
- The reconstituted solution of Cysview is colorless to pale yellow, clear to slightly opalescent, and free from visible particles.

Cysview® Reconstitution: Using a vial adapter

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Cysview is now reconstituted and ready for use.

On the syringe label, write down the date and time of reconstitution. The reconstituted solution can only be used up to two hours following reconstitution. Discard the unused solution after two hours.

Begin the procedure within 3 hours of instillation

- The cystoscopic examination should be initiated no less than 1 or more than 3 hours after Cysview is instilled in the bladder.
- Ideally, the procedure should begin within 30 minutes after the evacuation of Cysview from the bladder.
- If the patient does not retain Cysview in the bladder for 1 hour, wait for the full hour to pass before the cystoscopic examination begins.
- Efficacy has not been established when Cysview is retained for less than 1 hour.



For more details, please see the Full Prescribing Information in pocket.

Cysview® Instillation

1

Void urine prior to Cysview instillation via intravesical catheter.

2

Assemble urinary catheter kit

Attach the syringe containing the solution of Cysview to the catheter, do the following:

- Remove the syringe cap from the syringe that contains the reconstituted 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

Insert catheter using sterile technique.

4

Slowly **instill Cysview solution** into the bladder through the catheter, ensuring that the complete volume of the syringe (50 mL) is administered.

To speak with a member of our Nurse Support Team
email Cysview.Nurse.Programs@Photocure.com or call (609) 285-4115

CYSVIEW®
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Important Risk & Safety Information

Limitations of Use

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

Warnings and Precautions

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.

Contraindications

Cysview should not be used in patients with porphyria, gross hematuria, or with known hypersensitivity to hexaminolevulinate or any derivative of aminolevulinic acid. Cysview may fail to detect some malignant lesions. False-positive fluorescence may occur due to inflammation, cystoscopic trauma, scar tissue, previous bladder biopsy, and recent BCG therapy or intravesical chemotherapy. No specific drug interaction studies have been performed.

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Use in Specific Populations

Safety and effectiveness have not been established in pediatric patients. There are no available data on Cysview use in pregnant women. Adequate reproductive and developmental toxicity studies in animals have not been performed. Systemic absorption following administration of Cysview is expected to be minimal. There are no data on the presence of hexaminolevulinate in human or animal milk, the effects on a breastfed infant, or the effects on milk production. The development and health benefits of breastfeeding should be considered along with the mother's clinical need for Cysview and any potential adverse effects on the breastfed infant from Cysview or from the underlying maternal condition.

Use of the KARL STORZ D-Light C Photodynamic Diagnostic (PDD) System

Cysview is approved for use 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.

Prior to Cysview administration, read the Full Prescribing Information and follow the preparation and reconstitution instructions.



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