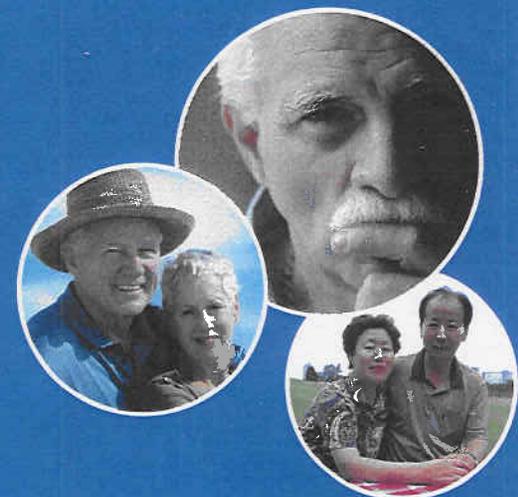


CYSVIEW[®]
HEXAMINOLEVULINATE HCL

Patient guide to
Cysview[®] blue light
cystoscopy for
detection of
bladder cancer



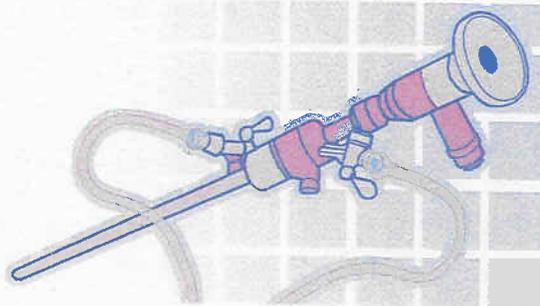
Only available by prescription
from your healthcare provider.

What is a cystoscope?

A thin, tube-like telescope called a cystoscope is carefully passed up the urethra (the tube through which urine leaves your body) and into the bladder. Tiny surgical instruments can be passed through the cystoscope so that samples of tissue can be removed (called a biopsy) then sent to the laboratory to be examined.

Cystoscopy also can be used for giving treatment directly to the bladder. Some procedures require a type of anesthesia. You may wish to discuss any questions about anesthesia with your healthcare provider. Your healthcare professional may instruct you to fast or have a light breakfast.

Image of a cystoscope



What is a Cysview blue light cystoscopy?

Cysview blue light cystoscopy helps your healthcare professional detect bladder cancer tumors. Healthcare professionals trained in cystoscopic procedures perform Cysview blue light cystoscopy, consisting of two parts: conventional white light and blue light. This test will be performed in the hospital operating room on an outpatient or inpatient basis.

Approximately 2 oz. of Cysview, a clear, colorless solution, is gradually delivered into the bladder (instilled) through a sterile plastic tube specific to this procedure; 1-1½ hours after the Cysview solution has been put into the bladder, the procedure will begin. Do not be alarmed if you cannot hold the solution in your bladder, but let your healthcare professional know if you experience problems.

During the procedure, the bladder is examined in white and blue light. Cysview accumulates in the tumor cells and glows pink under blue light. The tumor cells are highlighted and stand out against the normal bladder tissue, which keeps its blue appearance.

Cysview® (hexaminolevulinate hydrochloride) for Intravesical Solution Product Information

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.

Important Risk and Safety Information about Cysview

Product Risk Information:

Safety and effectiveness have not been established in patients receiving intravesical chemotherapy or BCG treatment within 3 months of Cysview photodynamic blue light cystoscopy, nor in pediatric patients.

The following adverse reactions have been identified during post-approval use of Cysview. Because these reactions are reported voluntarily from a population of uncertain size, it is not possible to reliably estimate their frequency or establish a causal relationship to drug exposure. Cases of anaphylactoid shock, bladder pain, cystitis and abnormal urinalysis have uncommonly been reported.

Cysview should not be used in patients with porphyria or with known hypersensitivity to hexaminolevulinate. There are no known drug interactions with hexaminolevulinate; however, no specific drug interaction studies have been performed.

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.

Please see Full Prescribing Information enclosed.

A glossary of terms is located at the end of this guide.

Why would my doctor order a Cysview blue light cystoscopy instead of the conventional cystoscopy procedure?

Under certain circumstances, a conventional cystoscopy may provide unclear results. To improve diagnostic accuracy, your healthcare professional may request a Cysview blue light cystoscopy.

Under conventional white light, tumors can be virtually invisible and are easily missed. Cysview is taken up faster by malignant cells, causing them to appear first under the blue light, making them easier to see.

Cysview may fail to detect some bladder tumors, including malignant lesions.

How safe is a Cysview blue light cystoscopy?

Any procedure may have some risks, and you should consult with your doctor regarding the risks and benefits of this procedure. The most common patient complaints include: bladder spasm, discomfort when passing urine; may experience frequent urination, pinkish tinge to the urine, bladder pain, procedural pain, urinary retention and headache. On rare occasions, patients receiving Cysview blue light cystoscopy have experienced increased heart rate, chest pain and fever.

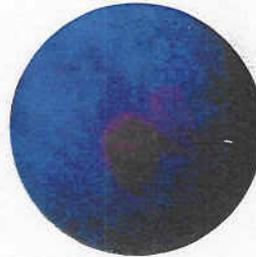
Please see Full Prescribing Information enclosed.

How your healthcare professional sees images during a Cysview blue light cystoscopy

Standard white light cystoscopy



Cysview® blue light cystoscopy



Cysview images supplied by Max Burger, MD

What to expect after the procedure

As your bladder will be full of water, it will probably be necessary to pass urine again once the procedure is finished. Most people, who have just had local anesthesia, feel ready to go home after a short time. Once home, it's usually recommended to rest for the remainder of the day.

If you had a biopsy, it takes a few days before the results are available.

It is not uncommon to have some bladder spasm after a cystoscopy. This may make you feel you may need to go to the bathroom more often. You may feel some stinging during passing urine for a day or two. Drinking plenty of water can help and also can prevent you from developing an infection. A pinkish tinge to the urine also is common for several days after the procedure, particularly if you have had some treatment.

Are there any complications?

Most patients do not have any unexpected problems or complications during or after a cystoscopy.

Some patients find it more difficult to pass urine afterwards. A catheter might need to be left in the bladder to drain excess fluid until swelling goes down.

A mild infection after cystoscopy may occur, but it can usually be treated with antibiotics.



When to seek advice from your doctor

If your urine still has a pinkish tinge, or you see blood clots after you have urinated several times, or if any symptoms are severe, or have not improved within two or three days, please contact your healthcare professional for advice.

Medications

Be sure to tell your healthcare professional all of the medications you are currently taking. Ask your doctor whether your medications should be taken before or held until after the procedure.

Glossary

Anaphylactic shock

Severe, whole-body allergic reaction.

BCG treatment (Bacille Calmette-Guerin)

As it pertains to bladder cancer, weakened tuberculosis bacteria that are placed into the bladder to decrease the recurrence of bladder cancer.

Bladder

A hollow organ that collects urine until it can be passed out of the body.

Chemotherapy

A type of cancer therapy, which uses anticancer drugs to selectively kill cancer cells.

Cystitis

Inflammation of the bladder; may be related to a bacterial infection, viral infection, radiation, or other bladder irritants.

Cystoscope

A telescope-like instrument that allows examination of the urethra and the inside of the bladder.

Glossary continued

Cystoscopy

The procedure of using a cystoscope to look into the urethra and bladder.

Fluorescence

The property of producing light when acted upon by radiant (shining brightly) energy.

Instill

To impart gradually

Intravesical

Within the bladder

Intravesical chemotherapy/cancer therapy

Medical therapy that is placed into the bladder to kill cancer cells. The therapy is placed into the bladder through a urethral catheter.

Malignant

A cancerous tumor; can invade surrounding structures and spread to a distant site.

PPD (Photodynamic Diagnosis)

A modern type of cystoscopy in which a special drug solution is instilled into the bladder about an hour before the procedure. The drug accumulates in the cancer cells and glows pink under blue light. The tumor cells are highlighted and stand out against the normal bladder tissue which keeps its blue appearance.

Additional patient information

Bladder Cancer Advisory Network (BCAN).
www.bcan.org

BCAN is the first national advocacy organization dedicated to increasing public awareness about bladder cancer; to advancing bladder cancer research; and to providing educational and support services for the bladder cancer community. Founded in May 2005, BCAN is a cooperative effort among bladder cancer survivors, their families and caregivers, and the medical community.

If you have any questions or concerns about your Cysview blue light cystoscopy, ask your doctor right away.

Your doctor will be able to explain every aspect of the procedure and test results. This patient guide is for informational purposes only; it does not replace an open conversation with your doctor.

Please see Full Prescribing Information enclosed.

Contact Photocure Inc:

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