

PART III: CONSUMER INFORMATION

Pr CYSVIEW™

hexaminolevulinate hydrochloride powder for intravesical solution

This leaflet is part III of a three-part "Product Monograph" published when Cysview was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about Cysview. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:

This medicine is used to help identify papillary bladder cancer. It is given before your doctor uses a special device called a 'cystoscope' to look inside of your bladder. A cystoscope helps to see possible tumors, and Cysview helps this process by making the tumor cells illuminate red under blue light, in addition to the usual white light used. After the tumor cells are detected, all the abnormal cells identified under blue light and white light are removed.

What it does:

Cysview is administered into your bladder through a catheter 1 hour before you are sent to the operating room for your cystoscopy examination, and it is taken up by tumor cells in the bladder lining. The tumors then light up in red when the blue light which is provided by the cystoscopic equipment is used in the examination.

When it should not be used:

- If you are allergic (hypersensitive) to the active ingredient or any other ingredients of Cysview (See What the important nonmedicinal ingredients are).
- If you have 'porphyria' (a rare inherited blood disease).

What the medicinal ingredient is:

Hexaminolevulinate hydrochloride

What the important nonmedicinal ingredients are:

Disodium phosphate dihydrate
Hydrochloric acid
Potassium dihydrogen phosphate
Sodium chloride
Sodium hydroxide
Water for injections

What dosage forms it comes in:

Cysview is supplied as a kit labeled Cysview (hexaminolevulinate hydrochloride powder for intravesical solution) 100 mg/vial, a kit for the preparation of intravesical solution. The kit contains:

- one vial of Cysview (hexaminolevulinate hydrochloride

powder) 100 mg in a 10 ml clear glass vial and

- one vial of diluent for Cysview, 50 ml in a polypropylene vial.

After mixing, the 50 ml Cysview solution for intravesical solution contains 1.7 mg/ml hexaminolevulinate (8 mmol/l).

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions

A serious life-threatening allergic reaction (anaphylaxis) has been reported following administration of Cysview by the healthcare professional (HCP). The HCP will have advanced life support facilities available in case of a reaction.

BEFORE you use Cysview, talk to your doctor if:

- you are allergic (hypersensitive) to the active ingredient or any other ingredients of Cysview, including the liquid used to dissolve it
- you have 'porphyria' (a rare inherited blood disease)
- you are pregnant or planning to become pregnant
- you are breast-feeding or planning to breast-feed.

The following conditions may cause local reactions in your bladder, which can make it more difficult for your doctor to interpret what he sees during the examination:

- If you have a urinary infection or burning feeling when you pass urine
- If you have had Bacillus Calmette-Guérin (BCG) therapy or chemotherapy on your bladder less than 90 days ago
- If you have had an operation on your bladder recently.

This product will be administered by a healthcare professional through a catheter. Cysview is irritating to the skin. In case of accidental contact/spillage of Cysview on the skin, the skin should be washed with soap and water, and dried.

INTERACTIONS WITH THIS MEDICATION

Drug interactions studies have not been done for Cysview. It is not known if any drug may interact with Cysview. Talk to your doctor if you are worried about this.

PROPER USE OF THIS MEDICATION

Usual adult dose:

One Cysview kit will provide one dose of 50 ml Cysview solution for administration into the bladder by the healthcare professional. The solution will need to stay in your bladder for 1-3 hours. Your doctor (healthcare professional) will monitor your condition for at least 30 minutes after administration of Cysview to watch

for allergic reactions.

Overdose:

If Cysview is kept in your bladder for more than 3 hours, no side effects are expected.

If you feel you have been given too much Cysview, speak to your attending healthcare professional for this procedure, even if there are no symptoms.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like all medicines, Cysview can cause side effects in some patients. There is a risk of side effects related to the examination technique (cystoscopy) used to look inside of your bladder. The following side effects may happen after blue light cystoscopy with Cysview.

Common side effects

Headache, pain and difficulty passing urine, feeling unable to empty your bladder (urinary retention), blood in your urine, pain after the examination (procedure).

If you have severe difficulties or are not able to empty your bladder after you have come home from the hospital, you should contact your physician.

Uncommon side effects

Feeling sick (nausea), vomiting, diarrhea, constipation, fever (high temperature), burning feeling when you pass urine (caused by inflammation or infection of your bladder), needing to pass urine more often, blood infection, not being able to sleep or difficulty going to sleep, pain in the tube called the ‘urethra’ that urine passes through, feeling like you need to pass urine right away (urgency), higher levels of white blood cells, increased levels of bilirubin (this is the yellowish pigment in your bile) or increased liver enzymes, these would all be seen in blood test results, lower levels of red blood cells (anaemia), inflammation of the head of the penis (balanitis), back pain, gout, rash.

Frequency not known

- Hypersensitivity reactions (blood pressure drop, increased heart rate, skin rash)

If any of the side effects get serious or have symptoms that you do not understand or find distressing, you should contact your physician immediately.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

	Symptom / effect	Contact your doctor	
		Only if severe	In all cases
Common	Feeling unable to empty your bladder (urinary retention)		X
	Blood in your urine Pain after the examination (procedure)	X	
Un-common	Fever (high temperature)	X	
	Blood infection (chills, rapid breathing, rapid heart rate, confusion, weakness, and red spots on the skin)		X
	Burning feeling when you pass urine (caused by inflammation or infection of your bladder) Needing to pass urine more often Pain in the tube called the ‘urethra’ that urine passes through Feeling like you need to pass urine right away (urgency) Inflammation of the head of the penis (balanitis) Rash	X	
Frequency not known	Anaphylactic shock: a severe body reaction with symptoms such as nausea, low blood pressure, fainting, weakness, fast or slow heartbeat, chills, tremor, feeling cold		X
	Hypersensitivity (allergic) reaction with symptoms such as itching, rash, hives, swelling of the mouth, throat and extremities, difficulty breathing		X

This is not a complete list of side effects. For any unexpected effects while taking Cysview, contact your doctor.

HOW TO STORE IT

Store Cysview (hexaminolevulinate hydrochloride) at 15°- 30°C.

If not administered shortly after reconstitution, the healthcare professional will store the solution for up to 2 hours in a refrigerator at 2°C - 8°C. If not used within 2 hours, the solution will be discarded.

Keep out of reach and sight of children.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect	Contact your doctor	
	Only if severe	In all cases

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

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- \$ Report online at
www.healthcanada.gc.ca/medeffect
 - \$ Call toll-free at 1-866-234-2345
 - \$ Complete a Canada Vigilance Reporting Form and:
 - Fax toll-free to 1-866-678-6789, or
 - Mail to: Canada Vigilance Program
Health Canada
Postal Locator 0701D
Ottawa, Ontario
K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be found at:

<http://www.cysview.ca> or by contacting the sponsor, BioSyent Pharma Inc., at:

1-888-439-0013

This leaflet was prepared by BioSyent Pharma Inc.

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