

## PATIENT MEDICATION INFORMATION

### READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PrCYSVIEW®

**Hexaminolevulinate hydrochloride for intravesical solution**

**100 mg/vial**

#### **Kit for the preparation of intravesical solution**

Read this carefully before you start taking **Cysview** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **Cysview**.

#### **Serious Warnings and Precautions**

Very rare cases of hypersensitivity (allergic reaction), including anaphylactic shock, have been reported when using Cysview. Tell your healthcare professional if you think you might be experiencing an allergic reaction during your procedure.

#### **What is Cysview used for?**

This medicine is used to help identify 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 tumours, and Cysview helps this process by making the tumour cells illuminate red under blue light. The medicine is used in addition to the usual white light procedure. After the tumour cells are detected, all the abnormal cells identified under blue light and white light are removed.

#### **How does Cysview work?**

Cysview is administered into your bladder through a catheter 1 hour before you are sent to the operating room for your cystoscopy examination. This allows Cysview to be taken up by tumour cells in the bladder lining. The tumours then light up in red when your doctor switches the cystoscopic equipment being used to the blue light mode.

#### **What are the ingredients in Cysview?**

Medicinal ingredients:	Hexaminolevulinate hydrochloride
Non-medicinal ingredients:	Disodium phosphate dihydrate
	Hydrochloric acid,
	Potassium dihydrogen phosphate
	Sodium chloride
	Sodium hydroxide
	Water for injections

**Cysview comes in the following dosage forms:**

Cysview is supplied as a kit labeled “Cysview (hexaminolevulinate hydrochloride) 100 mg, kit for the preparation of intravesical solution”. Each kit contains:

- 1 vial of Cysview (hexaminolevulinate hydrochloride powder), 100 mg in a 10 mL clear glass vial;
- 1 DILUENT for Cysview, 50 mL in a pre-filled syringe;
- 1 vial adapter.

**Do not use Cysview if:**

- You have ‘porphyria’ (a rare, inherited blood disease);
- You are hypersensitive to this drug or to any ingredient in the formulation or component of the container. For a complete listing, see the “What are the ingredients in Cysview?” section.

**To help avoid side effects and ensure proper use, talk to your healthcare professional before you take Cysview. Talk about any health conditions or problems you may have, including if you:**

- Can see blood in your urine;
- Are pregnant or planning to become pregnant;
- Are breast-feeding or planning to breast-feed.

**Other warnings you should know about:**

The following conditions may cause local reactions in your bladder, which can make it more difficult for your healthcare professional to interpret what he/she see 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 fewer than six weeks ago;
- If you have had an operation on your bladder recently.

This product will be administered by a healthcare professional through a catheter. Cysview may be 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.

**Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.**

**How to take Cysview:**

- Cysview will be given to you by a healthcare professional through a catheter before your procedure.
- Your healthcare professional will monitor your condition for at least 30 minutes after administration of Cysview to watch for allergic reactions.

**Usual 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.

**Overdose:**

If you think you, or a person you are caring for, have been given too much Cysview, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

**What are possible side effects from using Cysview?**

These are not all the possible side effects related to use of Cysview that you may have. If you experience any side effects not listed here, tell your healthcare professional.

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:**

- Feeling sick (nausea);
- vomiting;
- diarrhoea;
- constipation.

**Uncommon side effects:**

- Headache
- not being able to sleep or difficulty going to sleep;
- 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),
- back pain;
- gout.

Serious Side Effects and What To Do About Them			
Symptom / Effect	Talk to Your Healthcare Professional		Stop taking drug and get immediate medical help
	Only if Severe	In All Cases	
<b>COMMON</b>			
Feeling unable to empty your bladder (urinary retention)		X	
Blood in your urine	X		
Pain after the examination (procedure)	X		
Fever (high temperature)	X		
<b>RARE</b>			
Blood infection (chills, rapid breathing, rapid heart rate, confusion, weakness, or red spots on the skin)		X	

Serious Side Effects and What To Do About Them			
Symptom / Effect	Talk to Your Healthcare Professional		Stop taking drug and get immediate medical help
	Only if Severe	In All Cases	
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, itching	X		
<b>VERY RARE</b>			
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	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

### Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

*NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.*

**Storage:**

Store Cysview (hexaminolevulinate hydrochloride) between 15 °C–30 °C.

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

Keep out of reach and sight of children.

**If you want more information about Cysview:**

- Talk to your healthcare professional.
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>; the manufacturer's website: [www.cysview.ca](http://www.cysview.ca), or by calling 1-833-229-1037.

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