

PART III: CONSUMER INFORMATION

Pr CYSVIEW®

hexaminolevulinate hydrochloride powder
100 mg/vial
Kit for the preparation of 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 tumours, and Cysview helps this process by making the tumour cells illuminate red under blue light, in addition to the usual white light used. After the tumour 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 tumour cells in the bladder lining. The tumours 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 non-medical ingredients are**);
- If you have 'porphyria' (a rare inherited blood disease).

What the medicinal ingredient is:

Hexaminolevulinate hydrochloride

What the important non-medical ingredients are:

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

What dosage forms it comes in:

Cysview is supplied as a kit labeled Cysview (hexaminolevulinate HCl) 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.

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

Very rare cases of hypersensitivity, including anaphylactic shock, have been reported during post-marketing use of Cysview. Your doctor 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:

1 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 | |
| Uncommon | 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 | |
| | 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 |
| Frequency not known | 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) 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.

REPORTING SIDE EFFECTS

You can help improve the safe use of health products for Canadians by reporting serious and unexpected side effects to Health Canada. Your report may help to identify new side effects and change the product safety information.

3 ways to report:

- Online at [MedEffect](#)
- By calling 1.866.234.2345 (toll-free)
- By completing a Consumer Side Effect Reporting Form and sending it by:
 - Fax to 1.866.678.6789 (toll-free), or
 - Mail to Canada Vigilance Program
Health Canada, Postal Locator 1908C
Ottawa, ON K1A 0K9

Postage paid labels and the Consumer Side Effect Reporting Form are available at [MedEffect](#).

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.

MORE INFORMATION

This document plus the full Product Monograph, prepared for health professionals, can be found at: www.cysview.ca or by contacting the sponsor, BioSyent Pharma Inc., at: 1.888.439.0013.

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