

PART III: CONSUMER INFORMATION

Pr**ELMIRON**^{®*}
pentosan polysulfate sodium capsules

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

ABOUT THIS MEDICATION

What the medication is used for:

The treatment of inflammation and irritation of the bladder wall (interstitial cystitis).

What it does:

ELMIRON[®] is thought to adhere to the bladder surface supplementing the defective bladder layer. It is hypothesized that this action improves the symptoms of interstitial cystitis.

When it should not be used:

- Do not use **ELMIRON**[®] if you are allergic to pentosan polysulfate sodium, related compounds or any of the other ingredients.
- Do not use **ELMIRON**[®] if you have a personal history of eye disease that affects the retina.

What the medicinal ingredient is:

pentosan polysulfate sodium

What the nonmedicinal ingredients are:

gelatin capsule, magnesium stearate, microcrystalline cellulose, and titanium dioxide.

What dosage forms it comes in:

Capsules: 100 mg

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions

Do not use **ELMIRON**[®] if you have a personal history of eye disease that affects the retina.

Cases of retinal changes (pigmentary maculopathy) have been reported with long-term use of **ELMIRON**[®]. This eye disease changes the centre of the retina (called the 'macula'). This may harm your vision and may lead to a permanent decrease or loss of central vision. Tell your doctor and eye doctor right away if you notice any changes in your vision.

While taking **ELMIRON**[®], regular eye exams that include checking your retina are recommended for detection of pigmentary maculopathy. Your doctor will decide when these eye exams are needed, and if the treatment should be continued.

BEFORE you use **ELMIRON**[®] talk to your doctor or pharmacist if:

- You are taking anticoagulant therapy such as coumarin anticoagulants, heparin, tPA, streptokinase, high-dose ASA (acetylsalicylic acid) or anti-inflammatory drugs such as ibuprofen
- You are at increased risk of bleeding due to diseases such as ulcerative GI lesions (sores inside your digestive tract), aneurysms (balloon-like bulges in a blood vessel), or diverticulae (small protrusions of the lining of the intestine into the surrounding muscle).
- You will be undergoing surgery
- You are pregnant or breastfeeding
- You have liver problems
- You have a personal or family history of eye problems. Tell your doctor if you notice any changes in your vision.

The safety and effectiveness of **ELMIRON**[®] in children and adolescents below the age of 18 years have not been established.

INTERACTIONS WITH THIS MEDICATION

Since **ELMIRON**[®] is a weak anticoagulant (blood thinner), tell your doctor or pharmacist if you are taking any other anti-coagulant therapy such as warfarin, high-dose ASA (acetylsalicylic acid), and nonsteroidal anti-inflammatory drugs (NSAIDS).

PROPER USE OF THIS MEDICATION

Usual dose:

The recommended dose of ELMIRON® is 300 mg/day taken as one 100 mg capsule orally three times daily. The capsules should be taken with water at least 1 hour before meals or 2 hours after meals.

Overdose:

Call your doctor or go to the nearest hospital emergency department. Take the labelled medicine bottle with you.

Missed dose:

Take the dose as soon as you remember. If it is almost time for your next dose, skip the dose you missed and take your next dose. Do not double doses to make up for the missed dose.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

ELMIRON® is usually well tolerated. Reported adverse reactions are infrequent and usually do not require discontinuation of treatment. The most common reactions are associated with digestion, blood, and skin. Common reactions you may experience include nausea and hair loss. Other possible side effects include urticaria (hives), itching, and shortness of breath.

This medication can raise your liver enzymes. This can be confirmed by blood tests ordered by your doctor.

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

| Symptom / effect | | Talk with your doctor or pharmacist | | Stop taking drug and call your doctor or pharmacist |
|------------------|------------------------------|-------------------------------------|--------------|---|
| | | Only if severe | In all cases | |
| Common | Headache | ✓ | | |
| | Abdominal pain | ✓ | | |
| | Diarrhea | ✓ | | |
| | Rash | | ✓ | |
| | Abnormal liver function test | | ✓ | |
| | Blood in stool | | ✓ | |
| | Nose bleed | | ✓ | |
| | Gum bleeding | | ✓ | |
| Uncommon | Dizziness | ✓ | | |
| | Bruising | | ✓ | |
| | Allergic reactions | | | ✓ |

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

| Symptom / effect | | Talk with your doctor or pharmacist | | Stop taking drug and call your doctor or pharmacist |
|------------------|---|-------------------------------------|--------------|---|
| | | Only if severe | In all cases | |
| Unknown | Pigmentary Maculopathy (Eye disease that affects the retina): difficulty reading; slow adjustment to low or reduced light, blurry vision, blurry or wavy vision near or in the center of your field of vision | | ✓ | |

This is not a complete list of side effects. For any unexpected effects while taking ELMIRON®, contact your doctor or pharmacist.

HOW TO STORE IT

Store at controlled room temperature (15°C to 30°C).

Keep out of the reach of children.

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:

- Report online at www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.
- 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 1908C
Ottawa, ON 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.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting

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

For questions, concerns or full Product Monograph go to:
<http://www.janssen.com/canada>
or contact the manufacturer, Janssen Inc., at:
1-800-567-3331 or 1-800-387-8781

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Last revised: October 2020

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