

Consumer Medicine Information

PLEASE READ THIS LEAFLET CAREFULLY BEFORE YOU START TO USE YOUR MEDICINE

Keep the leaflet because you may want to read it again

It is very important that you read and understand this leaflet. If it is not clear or concerns you, talk to your doctor or pharmacist. This leaflet does not take the place of careful discussions with your doctor.

Remember, this leaflet has been written to answer many common questions but does not contain all the information about ELMIRON. Your doctor and pharmacist have more information.

What is ELMIRON?

ELMIRON is supplied in white opaque hard gelatin capsules, each capsule containing 100 mg pentosan polysulfate sodium (the active drug), microcrystalline cellulose and magnesium stearate. It is formulated for oral use.

The Australian Register Number is AUST R 48446.

What ELMIRON is used for and how it works

ELMIRON is an oral treatment for interstitial cystitis otherwise known as a chronic inflammation of the bladder wall. ELMIRON is passed by the kidneys into the urine, where it coats the damaged bladder wall. This improves the bladder's protective lining. After taking ELMIRON, it may be at least six to eight weeks before you notice improvement in your symptoms.

Advice before using ELMIRON

Use ELMIRON only when prescribed by your doctor.

All medicines have benefits and risks. In deciding to give you ELMIRON, your doctor has weighed the risks of taking ELMIRON against the benefits he/she expects it will have for you.

When should I not use ELMIRON?

ELMIRON should not be used by people who:

- have known hypersensitivity to these kinds of drugs,
- have haemophilia,
- have active (or a recent history of) bleeding,
- are currently using heparin or oral anti-coagulant therapy,
- are pregnant, or intend to become pregnant,
- are less than 18 years of age.

If you are not sure whether you should start using ELMIRON, contact your doctor.

When should I be careful using ELMIRON?

If you have a bleeding disorder, or you are taking anti-coagulant therapy, or you are at greater risk of bleeding (e.g. you are an alcoholic), you should tell your doctor before beginning treatment with ELMIRON.

Eating and drinking (e.g. milk, tea, coffee) interferes with the absorption of ELMIRON and so it is very important that you do not eat or drink for one hour after taking ELMIRON and that you take ELMIRON at least two hours after meals.

Call your doctor (including eye doctor) if you notice any changes in your vision.

Should I use ELMIRON during pregnancy or breast-feeding?

- **Pregnancy**
ELMIRON should **not** be used during pregnancy. You should tell your doctor if you are pregnant or intend to become pregnant.
- **Breast-feeding**
Do not use ELMIRON while breast-feeding. If you intend to breast feed, consult your doctor.

Am I restricted in my daily activities while using ELMIRON?

There are no known restrictions associated with taking ELMIRON.

Should I use ELMIRON with other medicines?

There are some medicines which may affect the way ELMIRON works. Tell your doctor about any other medicines that you take, especially heparin or oral anti-coagulant therapy. Also tell your doctor about all the medicines you have bought without a doctor's prescription.

How to use ELMIRON properly

How much ELMIRON should I take?

The dose will be decided by your doctor and will depend on your condition. Do not take more capsules than you have been prescribed.

When should I take ELMIRON?

Normally, you should take ELMIRON three times a day unless your doctor tells you to do otherwise. Follow the pharmacist label on the pack. For the best results take the capsules at the same time each day. This will also help you to remember.

It is very important that you take ELMIRON:

- with a small glass of water,
- **at least 2 hours after eating food or drinking,** and
- that you **do not eat food or drink** for one hour after taking ELMIRON.

It is suggested that you take ELMIRON when your stomach is empty.

How long do I need to take ELMIRON?

ELMIRON controls your condition but does not cure it. Therefore ELMIRON must be taken every day. Continue taking ELMIRON for as long as your doctor prescribes. If you stop taking ELMIRON, the positive effects may gradually wear off.

What if I miss a dose?

If you miss taking your ELMIRON, skip the missed dose and take your next dose as you normally would. If you have trouble remembering to take your tablets, talk to your pharmacist for some helpful hints.

Further information

Doctor's prescription required: Yes.

Regular examinations or tests: Various tests should be monitored periodically if you are taking ELMIRON on a long term basis. Your doctor will advise you regarding these tests.

Surgery: Tell your dentist or doctor that you are taking ELMIRON if you plan on having surgery.

Habit-forming potential: ELMIRON is **not** addictive.

Remember: This medicine is for **you**. Only a doctor can prescribe it for you. Never give it to someone else. It may harm them even if they have the same condition as you.

What unwanted effects may ELMIRON cause?

If your bladder condition or symptoms become worse, you should consult your doctor immediately and **stop** taking ELMIRON.

Some people may experience mild effects of swelling, headache, dizziness, nausea, indigestion, or diarrhoea. If any of these occur and are bothersome, contact your doctor. Other unwanted effects not listed may also occur in some patients. Tell your doctor if you notice any other effects.

Rare cases of retinal disorders (pigmentary maculopathy) have been reported with use of Elmiron (especially after long term use). Tell your doctor immediately if you experience visual changes such as reading difficulty and slower adjustment to low or reduced light. Your doctor will discuss with you whether the treatment should be continued. For early detection of retinal disorders, eye examination will be performed.

In case of overdose

If you accidentally take too many capsules, you should contact your Doctor or contact the Poisons Information Centre on 131126 (Australia) There are no known instances of people suffering damage from taking too much ELMIRON.

How should I store ELMIRON?

- Keep ELMIRON out of the reach of children.
- Keep the capsules away from sunlight and away from the damp and store in a cool place. Therefore, do not store ELMIRON in the bathroom or near the kitchen sink.
- Keep ELMIRON in the bottle given to you by your pharmacist.
- Do not use the capsules past the expiry date on the bottle.
- If your doctor tells you to stop taking ELMIRON, return any left over capsules to your pharmacist for disposal.

Where should I go for further information?

This is not all the information that is available on ELMIRON. If you have any more questions or are not sure about anything, ask your doctor or pharmacist.

Arthropharm Pty Ltd is committed to the better health of all Australians. Consumer Product Information is part of this commitment.

Arthropharm Pty Limited

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