B. PACKAGE LEAFLET

Package leaflet: Information for the patient

elmiron 100 mg hard capsules
pentosan polysulfate sodium

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What elmiron is and what it is used for

elmiron is a medicine that contains the active substance pentosan polysulfate sodium. After taking the medicine, it passes into the urine and attaches to the lining of the bladder, helping to form a protective layer.

elmiron is used in adults to treat **bladder pain syndrome** characterised by many tiny bleeds or distinctive lesions on the bladder wall and moderate to severe pain and a frequent urge to urinate.

2. What you need to know before you take elmiron

Do not take elmiron if you are

- **allergic** to pentosan polysulfate sodium or any of the other ingredients of this medicine (listed in section 6)
- **bleeding** (other than menstrual bleeding)

Warnings and precautions

Talk to your doctor or pharmacist before taking elmiron if you have:
- to undergo surgery
- a blood clotting disorder or increased risks of bleeding, such as using a medicine that inhibits blood clotting
- ever had a reduced number of blood platelets caused by the medicine called heparin
- reduced liver or kidney function

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 difficulty when reading, visual distortions, altered colour vision and/or 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 regularly.

Children and adolescents

elmiron **is not recommended** in children under 18 years as safety and efficacy have not been established in this group.

Other medicines and elmiron

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Inform your doctor or pharmacist, particularly if you use medicines that prevent blood clotting, or painkillers that reduce blood clotting.

Pregnancy and breast-feeding

elmiron **is not recommended** during pregnancy or breast-feeding.

Driving and using machines

elmiron has no or negligible influence on the ability to drive and use machines.

elmiron contains sodium.
This medicine contains less than 1 mmol sodium (23 mg) per capsule, that is to say essentially 'sodium-free'.

3. How to take elmiron

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is:
1 capsule, 3 times daily
Your doctor will assess your response to elmiron every 6 months.

Method of use

Take the capsules whole with one glass of water, at least 1 hour before or 2 hours after meals.

If you take more elmiron than you should

Inform your doctor in case of overdose. Stop taking elmiron if side effects occur until they disappear.

If you forget to take elmiron

Do not take a double dose to make up for a forgotten capsule.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Side effects have been observed with the following frequencies:
Common: may affect up to 1 in 10 people

- infections, flu
- headache, back pain
- dizziness
- nausea, indigestion, diarrhoea, abdominal pain, abdomen enlarged
- rectal bleeding
- accumulation of fluid in arms or legs
- hair loss
- weakness, pelvic (lower abdomen) pain
- need to urinate more frequently than usual
- abnormal liver function

Uncommon: may affect up to 1 in 100 people
- lack of blood platelets, red or white blood cells
- bleeding, including small bleeding beneath the skin
- allergic reactions, increased sensitivity to light
- loss of appetite, weight gain or loss
- severe mood swings or depression
- increased sweating, sleeplessness
- restlessness
- abnormal sensation such as prickling, tingling and itchiness
- flow of tears, lazy eye
- ringing or buzzing in the ears
- breathing difficulties
- indigestion, vomiting, wind, difficulty passing stools
- mouth ulcer
- skin rash, increased mole size
- joint or muscle pain

Not known: frequency cannot be estimated from the available data
- blood clotting disorders
- allergic reactions
- abnormal liver function

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via Yellow Card Scheme.
Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.
By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store elmiron

Keep this medicine out of the sight and reach of children.

- **bottle**

Do not use this medicine after the expiry date which is stated on the label and carton after EXP. The expiry date refers to the last day of that month.

Keep the bottle tightly closed in order to protect from moisture.
After first opening: use within 45 days. Dispose any remaining capsules after this period.

- **blister**

Do not use this medicine after the expiry date which is stated on the carton and blister after EXP. The expiry date refers to the last day of that month.

Do not store above 30 °C.

Do not throw away any medicines via wastewater. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What elmiron contains

- The active substance is pentosan polysulfate sodium.
  One hard capsule contains 100 mg pentosan polysulfate sodium.
- The other ingredients are microcrystalline cellulose, magnesium stearate, gelatin, titanium dioxide (E171).

What elmiron looks like and contents of the pack

The hard capsules are white and non-transparent, provided in a plastic bottle with child resistant closure or plastic/aluminium blisters, packed in a carton.

- **bottle**

Each carton contains 90 capsules.
Each carton contains 300 (3 bottles x 100) capsules.

- **blister**

Each carton contains 90 capsules.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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Detailed information on this medicine is available on the European Medicines Agency website http://www.ema.europa.eu.