PRESCRIBING FACT SHEET

Please refer to full Summary of Product Characteristics before prescribing

A guide for UK HCPs prescribing elmiron®

elmiron®
pentosan polysulfate sodium

INDICATION

elmiron® is indicated for the treatment of bladder pain syndrome (BPS) characterised by either glomerulations or Hunner's lesions in adults with moderate to severe pain, urgency and frequency of micturition.

DOSAGE

Adults: 300 mg/day taken as one 100 mg capsule **orally three times daily,** with water at least 1 hour before or 2 hours after meals.

The response to **elmiron®** takes time, as the glycosaminoglycan (GAG) layer in the bladder heals. In clinical trials, a response was seen within 3 months.[1-3]

Patients should be reassessed every 6 months:

- If there is no improvement in symptoms after 6 months, treatment should be stopped.
- **elmiron®** treatment should be continued for as long as a response is maintained.

SPECIAL POPULATIONS

elmiron® has not been specifically studied in special patient populations like elderly or patients with renal or hepatic impairment. No dose adjustment is recommended for these patients.

HEALTH TECHNOLOGY APPRAISALS

elmiron® received a positive appraisal from NICE, AWMSG and SMC.[4-6] **For details scan here.**

elmiron® should be used in patients that have not responded to an adequate trial of standard, less expensive oral treatments.[4]

The clinical experts advised NICE that **elmiron®** would generally be used before bladder instillations or for people who could not have bladder instillations.[4]

Consilient Health has a Patient Access Scheme (PAS) in place that makes **elmiron®** available to the NHS with a discount.

INTERACTIONS

Due to the weak anticoagulant effect of **elmiron®**, patients who are concomitantly treated with anticoagulants, heparin derivatives, thrombolytic or antiplatelet agents including acetylsalicylic acid, or nonsteroidal anti-inflammatory medicinal products should be evaluated for any haemorrhagic event in order to adapt the dose if needed.

PREGNANCY & BREASTFEEDING

elmiron® is not recommended during pregnancy and should not be used during breastfeeding.

TOLERABILITY

Common adverse events reported from the clinical trials were headache, dizziness and gastrointestinal events. These were comparable to those reported under treatment with placebo in regards to quality and quantity.

Alopecia has been reported, causing apparent thinning of hair in some patients. The SmPC lists alopecia as 'common', occurring in ≥1/100 to <1/10 patients, with data from a long-term study reporting an incidence of 1 in 25.[7] Thinning of hair has been observed with all heparin-like products. The thinning of hair is reversible after cessation of treatment.[8]

SPECIAL WARNINGS & PRECAUTIONS

elmiron® is a weak anticoagulant, therefore patients undergoing surgery or who have an underlying coagulopathy or increased risk of bleeding should be evaluated for haemorrhagic events.

elmiron® can be used in patients with renal or hepatic insufficiency and no dose adjustment is recommended; however, these patients should be carefully monitored.

Rare cases of pigmentary maculopathy have been reported, especially after long-term use.

- Via a literature search conducted for an EMA periodic safety review in January 2020, publications were identified reporting of 35 patients who were diagnosed with maculopathy. They have been treated long-term with **elmiron®**.[9,10]
- There has been no causal link established between treatment with **elmiron®** and maculopathy.[11]
- All patients should have an eye test at 6 months, e.g., at an opticians,[12] for early detection of maculopathy at 6 months after initiation and then every 5 years thereafter (or earlier, in case of visual complaints). The patient should inform the optician they take **elmiron®**. *Patient information leaflets are available from the **elmiron®** team, see details on reverse.*
- If any relevant ophthalmological findings are noted, examinations should be conducted annually, and treatment cessation considered.

CONTRAINDICATIONS

Hypersensitivity to the active substance or to any of the excipients (microcrystalline cellulose, magnesium stearate, gelatin, titanium dioxide (E171)).

Due to the weak anticoagulant effect, **elmiron®** must not be used in patients who actively bleed (menstruation is not a contraindication).

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Consilient Health (UK) Ltd, No. 1 Church Road, Richmond upon Thames, Surrey TW9 2QE UK or drugsafety@consilienthealth.com

Discover more at www.bladderpain.co.uk

Prescribing information can be found on the back page

Consilient Health

elmiron®

pentosan polysulfate sodium

For more information and to access patient support materials, visit:

www.bladderpain.co.uk

Contact your elmiron® team for more information
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Libby Samuels: **lsamuels@consilienthealth.com**

References

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elmiron® (pentosan polysulfate sodium) Prescribing Information. Please refer to the elmiron® Summary of Product Characteristics for full details.

Product name: elmiron® 100 mg hard capsules **Composition:** 100mg of pentosan polysulfate sodium **Indication:** Treatment of bladder pain syndrome characterized by either glomerulations or Hunner's lesions in adults with moderate to severe pain, urgency and frequency of micturition. **Dosage and administration: Adults:** One capsule three times daily. Reassess treatment response every 6 months. Discontinue if no improvement in the 6 months after initiation. Continue treatment as long as the response is maintained. **Special populations:** No dose adjustment recommended. **Paediatric population:** Safety and efficacy has not been established. **Method of administration:** Take with water at least 1 hour before or 2 hours after meals. **Contraindications:** Hypersensitivity to active substance(s) or any of the excipients. Patients who actively bleed (menstruation is not a contraindication). **Warnings and precautions (see SmPC for full details):** Diagnosis of other urologic disorders should be eliminated. Evaluate patients for haemorrhagic events if undergoing invasive procedures or having signs/symptoms of underlying coagulopathy or increased risk of bleeding. Monitor patients with a history of heparin or pentosan polysulfate sodium induced thrombocytopenia; or hepatic or renal insufficiency. Rare cases of pigmentary maculopathy have been reported, especially after long term use. Visual symptoms might include difficulty when reading, visual distortions, altered colour vision and/or slow adjustment to low/reduced light. All patients should have an ophthalmologic examination after 6 months, and, if there are no pathologic findings, regularly after 5 years (or earlier, in case of visual complaints). However, in case of relevant ophthalmologic findings, conduct yearly examinations. In such situations, treatment cessation should be considered. **Pregnancy:** Not recommended. **Breast-feeding:** Should not be used. **Fertility:** No information available. **Undesirable effects: Common (≥1/100 to <1/10):** Infections, influenza, headache, dizziness, nausea, diarrhoea, dyspepsia, abdominal pain, abdomen enlarged, rectal haemorrhage, peripheral oedema, alopecia, back pain, urinary frequency, asthenia, pelvic pain. **Uncommon (≥1/1,000 to <1/100):** Anaemia, ecchymosis, haemorrhage, leukopenia, thrombocytopenia, photosensitivity, anorexia, weight gain, weight loss, severe emotional lability/depression, increased sweating, insomnia, hyperkinesia, paraesthesia, lacrimation, amblyopia, tinnitus, dyspnoea, indigestion, vomiting, mouth ulcer, flatulence, constipation, rash, increased mole size, myalgia, arthralgia. **Not known** Allergic reactions, liver function abnormalities. **NHS Price:** £450.00 per bottle of 90 capsules. **Legal Classification:** POM **MA numbers:** EU/1/17/1189/001, PLGB 12404/0001 **Marketing Authorisation Holder:** bene-Arzneimittel GmbH, Herterichstrasse 1-3, D-81479 Munich, Germany. **Further information is available on request from:** Consilient Health (UK) Ltd, No.1 Church Road, Richmond upon Thames, Surrey TW9 2QE or drugsafety@consilienthealth.com. **Job Code:** UK-ELM-269 **Date of preparation of PI:** May 2021

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