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.

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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

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