Cystadrops® (cysteamine [as mercaptamine hydrochloride]) PRESCRIBING INFORMATION
Please refer to full Summary of Product Characteristics (SmPC) before prescribing

Name of Medicinal Product: Cystadrops 3.8 mg/mL eye drops solution. **Composition:** Mercaptamine hydrochloride equivalent to 3.8 mg mercaptamine (cysteamine). **Indications:** Cystadrops is indicated for the treatment of corneal cystine crystal deposits in adults and children from 2 years of age with cystinosis. **Dosage and Administration:** Treatment with Cystadrops should be initiated under the supervision of a physician experienced in the management of cystinosis. *Posology in adults & children (≥ 2 years of age):* The recommended dose is one drop in each eye, 4 times a day during waking hours, with an interval between each instillation of 4 hours. The dose could be decreased progressively (to a minimum total daily dose of 1 drop in each eye) depending on the results of ophthalmic examination (such as, corneal cystine crystal deposits, photophobia). If the patient misses an instillation, the patient should be told to continue the treatment with the next instillation. The dose should not exceed 4 drops a day in each eye. The accumulation of corneal cystine crystals increases if Cystadrops is discontinued. The treatment should not be stopped. *Method of administration:* Cystadrops is for ocular use only. Before first administration, patient should be told to bring back Cystadrops to room temperature. After opening, dropper bottle should be kept at room temperature and discarded after 7 days of use. **Contraindications:** Hypersensitivity to the active substance or to any of the excipients listed in section 6.1 of the SmPC. **Special Warnings and Precautions for Use:** Cystadrops contains benzalkonium chloride which may cause eye irritation. Benzalkonium chloride has been reported to cause punctate keratopathy and/or toxic ulcerative keratopathy. Monitoring is required. *Contact lenses:* Due to possible discolouration by benzalkonium chloride avoid contact with soft contact lenses. Patients should wait at least 15 minutes before re-inserting contact lenses. **Interactions:** No interaction studies have been performed. No interactions with orally administered medicinal products are anticipated. **Pregnancy and Lactation:** Systemic exposure of cysteamine following ocular administration is lower than following oral administration. Precautions should be taken with concomitant treatment with oral cysteamine. *Pregnancy:* The effect on pregnancy of untreated cystinosis is also unknown. Oral cysteamine should not be used during pregnancy, particularly during the first trimester, unless clearly necessary. Teratogenesis has been demonstrated in animals. *Breast-feeding:* Women taking oral cysteamine should not breast-feed. **Effects on ability to drive and use machines:** Cystadrops may have a temporary minor influence on the ability to drive and use machines. **Side Effects:** The most common adverse reactions are eye pain, ocular hyperaemia, eye pruritus, lacrimation increased, blurred vision or eye irritation. The majority of these adverse reactions are transient and most are mild or moderate. *Very common (≥ 1/10):* eye pain, vision blurred, eye irritation, ocular hyperaemia, eye pruritus, lacrimation increased, deposit eye and instillation site discomfort (mainly sticky eyes and sticky eyelashes); *Common (≥ 1/100 to < 1/10):* abnormal sensation in eye, dry eye, foreign body sensation in eye, eyelid oedema, eyelid irritation, visual impairment, hordeolum and instillation site pain. **Please consult the full SmPC for further information.** **Marketing Authorisation Numbers:** EU/1/15/1049/001. PLGB 15266/0021. **Price:** 5 ml = £865.00. **Legal Classification:** POM. **Name and Address of the Business Responsible for Sale:** Recordati Rare Diseases UK Ltd., Breakspear Park, Breakspear Way, Hemel Hempstead, HP2 4TZ. Further information is available on request. **Date Prescribing Information Revised:** January 2023.

Adverse events should be reported. Reporting forms and information can be found at **(UK)** https://yellowcard.mhra.gov.uk/ or search for MHRA Yellow Card in the Google Play or Apple App Store. (**Ireland)** Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance www.hpra.ie. Adverse events should also be reported to Recordati Rare Diseases at Tel: +44 (0)1491 414 333 or RRDpharmacovigilance@recordati.com