



Norgine welcomes TGA registration in Australia of PEDMARQSIÂ® (sodium thiosulfate anhydrous) for the prevention of cisplatin-induced hearing loss in children¹

Descrizione

COMUNICATO STAMPA â?? CONTENUTO PROMOZIONALE

AMSTERDAM, May 5, 2026 /PRNewswire/ â?? Norgine, a leading European specialty pharmaceutical company is pleased to announce that PEDMARQSIÂ® (sodium thiosulfate anhydrous) has been registered by the Australian Therapeutic Goods Administration (TGA) for the prevention of ototoxicity induced by cisplatin chemotherapy in patients 1 month to <18 years of age with localised, non-metastatic, solid tumours.Â¹

Cisplatin is a widely used and important chemotherapeutic for children with solid tumours, but it carries a substantial risk of permanent hearing loss. Hearing loss in childhood can have profound and lifelong consequences, affecting speech and language development, education, social functioning and overall quality of life.^{2,3} PEDMARQSIÂ® is the first and only treatment registered in Australia for the prevention of cisplatin-induced ototoxicity in paediatric patients.Â¹

Gus Rudolph, General Manager, Norgine, Australia, said: â??The TGA registration of PEDMARQSIÂ® marks an important milestone for children, families and healthcare professionals in Australia. Cisplatin-induced hearing loss can have lifelong consequences for young patients, and this approval provides an option specifically developed to help prevent this complication in eligible children receiving cisplatin chemotherapy. We are pleased to reach this regulatory milestone and remain focused on working with relevant stakeholders to support access for eligible patients in Australia.â?•

The TGA registration is based on data from two open-label, randomised Phase 3 clinical trials, SIOPEL 6Â² and COG ACCL0431.Â³

â??Cisplatinâ??induced hearing loss is a wellâ??recognised and often irreversible complication of paediatric cancer treatment, with significant longâ??term implications for communication, learning and

quality of life," said Dr. David Gillen, Chief Medical Officer, Norgine. "From a clinical perspective, the ability to proactively address this risk is an important consideration when caring for children receiving cisplatin. The availability of an approved preventive option represents a meaningful development in the supportive care of paediatric oncology patients."

Marketing authorisation for PEDMARQSI® in Australia adds to previous approvals in other territories, including Paediatric Use Marketing Authorisation (PUMA) granted by the European Medicines Agency in May 2023 and a national marketing authorisation in the United Kingdom, as well as Swissmedic approval in March 2026.^{4,5} This milestone further reflects Norgine's ability to navigate regulatory pathways for rare and specialist medicines.

PEDMARQSI® is not currently included on the Pharmaceutical Benefits Scheme (PBS). Please refer to the PEDMARQSI

® Consumer Medicines Information (CMI)⁸ for full safety information on risks, side effects and precautions including the risk of allergic reaction, nausea and vomiting, and electrolyte imbalance (sodium, potassium, magnesium and phosphate).

About PEDMARQSI® PEDMARQSI® is a formulation of sodium thiosulfate anhydrous, specifically developed and manufactured for the prevention of cisplatin induced hearing loss in patients aged 1 month to <18 years with localised, non-metastatic solid tumours. It is the first and only preventative treatment developed for cisplatin induced ototoxicity in this patient population.^{1,6,7}

Marketing authorisations for PEDMARQSI® were based on safety and efficacy data from two open label, randomised Phase III trials: SIOPEL 6 and COG ACCL0431.^{2,3}

For more information on PEDMARQSI® find the CMI here: PEDMARQSI
® Consumer Medicines Information (CMI)⁸ or at the Therapeutic Goods Administration at <https://www.tga.gov.au/>.

About Norgine Norgine is a mid-sized EU-based pharmaceutical company with 1,500 employees, generating approximately \$650 million in annual sales. At Norgine, innovation drives our mission to deliver medicines that change lives. From common conditions like constipation to rare and severe diseases such as childhood cancer, we target unmet medical needs because we believe that every scientific breakthrough deserves to reach patients in need.

We use our innovative development, commercialisation and manufacturing capabilities as well as strategic partnerships to navigate complex pathways. Combined with our extensive history and deep regional expertise, this approach allows us to accelerate and expand the reach of life-changing medicines across Europe, Australia, and New Zealand.

We are guided by the trust that healthcare professionals and patients place in us and remain committed to delivering innovation that transforms lives, one patient at a time.

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References:

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