



Norgine announces Swissmedic approval of PEDMARQSIÂ® for the prevention of cisplatin induced hearing loss in children

Descrizione

COMUNICATO STAMPA - CONTENUTO PROMOZIONALE

AMSTERDAM, March 26, 2026 /PRNewswire/ - Norgine B.V., a leading European specialty pharmaceutical company today announced that Swissmedic has granted marketing authorisation for PEDMARQSIÂ® (sodium thiosulfate solution for infusion) indicated for the prevention of cisplatin induced ototoxicity (hearing loss) in patients aged 1 month to <18 years with localised, non-metastatic solid tumours.

PEDMARQSIÂ® is the first and only pharmacological treatment specifically developed to prevent cisplatin induced hearing loss in children. While cisplatin remains a cornerstone of paediatric cancer treatment, it is associated with a high risk of irreversible, bilateral hearing loss that can begin with the first dose and progress over time. Hearing loss can have a profound and lasting impact on a child's speech and language acquisition, education, psychosocial development and overall quality of life.

Rüdiger Merkel, General Manager, DACH, Norgine, said: "The Swissmedic approval of PEDMARQSIÂ® represents an important milestone for children, families and healthcare professionals in Switzerland, where no approved pharmacological option has previously been available to help prevent this complication of cisplatin treatment. Hearing loss can have a lifelong impact on young patients, and this approval supports access to a treatment developed specifically to address this unmet medical need."

The Swissmedic approval is based on clinical evidence from two open label, randomised Phase 3 trials. Across these studies, treatment with sodium thiosulfate administered alongside cisplatin resulted in approximately a 50% reduction in the occurrence of cisplatin-induced ototoxicity compared with cisplatin alone, while maintaining the efficacy of chemotherapy.^{2,3}

PEDMARQSIÂ® has previously been granted paediatric use marketing authorisation (PUMA) by the European Medicines Agency (EMA) in May 2023 in the European Union and a national marketing authorisation in the United Kingdom.^{4,5} Together, these approvals reflect Norgine's ability to successfully navigate diverse European regulatory pathways for rare and specialist medicines.

About PEDMARQSIÂ®

PEDMARQSIÂ® is a novel formulation of anhydrous sodium thiosulfate, specifically developed and manufactured for the prevention of cisplatin induced hearing loss in patients aged 1 month to <18 years with localised, nonmetastatic solid tumours. It is the first and only preventative treatment developed for cisplatin induced ototoxicity in this patient population.¹

Marketing authorisations for PEDMARQSIÂ® were based on safety and efficacy data from two open label, randomised Phase III trials: SIOPEL 6 (pivotal) and Clinical Oncology Group (COG) ACCL0431.^{2,3} Across these studies, sodium thiosulfate significantly reduced the risk of hearing loss associated with cisplatin chemotherapy. The trials demonstrated a favourable tolerability profile, with nausea and vomiting being the most commonly reported adverse events, and infection, anaemia and neutropenia being the most common grade 3-4 adverse events.^{2,3}

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.

References:

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