

PEDMARK: A Sound Choice for CIO Risk Reduction

Clinical drug compendia show that PEDMARK can play an integral role in helping to reduce the risk of cisplatin-induced ototoxicity (CIO)^{1,2}



PEDMARK is the first and only FDA-approved therapy to reduce the risk of CIO¹⁻³

Please see below for full indication and Important Safety Information

As of May 2025, all clinical drug compendia recognized by the Centers for Medicare & Medicaid Services (CMS) have published PEDMARK drug monographs		
Compendia	Recommendation	Evidence Status
American Hospital Formulary Service (AHFS)	PEDMARK® (sodium thiosulfate injection) is indicated to reduce the risk of cisplatin-induced ototoxicity (CIO) caused by irreversible damage to the hair cells in the cochlea. ⁴	Supported based on FDA-approved clinical outcomes
Merative Micromedex® DrugDex®	PEDMARK® (sodium thiosulfate injection) is indicated to reduce the risk of hearing loss in patients ≥1 month with localized, non-metastatic solid tumors. In 2 clinical trials of cisplatin-treated pediatric patients, PEDMARK significantly reduced the relative risk of hearing loss compared to cisplatin alone. PEDMARK® (sodium thiosulfate injection, otic agent) is not substitutable with STS antidote products. Such substitutions may cause cardiac events and other serious reactions.⁵	Level of Evidence Rating: EFFICACY: Pediatric - Effective RECOMMENDATION: Pediatric - Class IIa - Recommend, In Most Cases STRENGTH OF EVIDENCE: Pediatric - Category A
Wolters Kluwer UpToDate™ Lexidrug®	PEDMARK® (sodium thiosulfate injection) reduces the risk of ototoxicity associated with cisplatin in pediatric patients ≥1 month of age with localized, nonmetastatic solid tumors by neutralizing cisplatin to produce an inactive platinum complex. ⁶	FDA approved - no panel review required
Elsevier Clinical Pharmacology powered by ClinicalKey®	PEDMARK® (sodium thiosulfate injection) is indicated for ototoxicity prophylaxis associated with cisplatin treatment in pediatric patients 1 month of age or older with localized, nonmetastatic solid tumors. ⁷	Supported based on FDA-approved clinical outcomes

The confirmed updates in the clinical drug compendia as listed above support integrating PEDMARK into your existing electronic medical record systems. Additionally, updates to include PEDMARK may be made-to-order sets containing cisplatin-based treatments.

INDICATIONS AND USAGE

PEDMARK (sodium thiosulfate injection) is indicated to reduce the risk of ototoxicity associated with cisplatin in pediatric patients 1 month of age and older with localized, non-metastatic solid tumors.

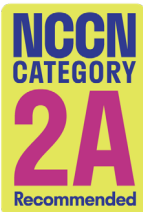
Limitations of Use

The safety and efficacy of PEDMARK have not been established when administered following cisplatin infusions longer than 6 hours. PEDMARK may not reduce the risk of ototoxicity when administered following longer cisplatin infusions, because irreversible ototoxicity may have already occurred.

Please see full [Prescribing Information](#), including Patient Product Information, or go to [PEDMARKhcp.com](https://www.pedmarkhcp.com).

Recommended for the Adolescent and Young Adult (AYA) population* by the National Comprehensive Cancer Network® (NCCN®)

These recommendations are not consistent with the FDA indication. Always refer to the PEDMARK Prescribing Information and Instructions for Use.



NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Adolescent and Young Adult* (AYA) Oncology recommends sodium thiosulfate (PEDMARK) as a Category 2A preventative treatment option to reduce the risk of hearing loss associated with cisplatin chemotherapy in patients with localized, non-metastatic solid tumors⁸

*NCCN Guidelines® define an adolescent or young adult (AYA) oncology patient as an individual between 15 and 39 years.

NCCN makes no warranties of any kind whatsoever regarding their content, use of application and disclaims any responsibility for their application or use in any way.

IMPORTANT SAFETY INFORMATION

- PEDMARK is contraindicated in patients with history of a severe hypersensitivity to sodium thiosulfate or any of its components.
- Hypersensitivity reactions occurred in 8% to 13% of patients in clinical trials. Monitor patients for hypersensitivity reactions. Immediately discontinue PEDMARK and institute appropriate care if a hypersensitivity reaction occurs. Administer antihistamines or glucocorticoids (if appropriate) before each subsequent administration of PEDMARK. PEDMARK may contain sodium sulfite; patients with sulfite sensitivity may have hypersensitivity reactions, including anaphylactic symptoms and life-threatening or severe asthma episodes. Sulfite sensitivity is seen more frequently in people with asthma.
- PEDMARK is not indicated for use in pediatric patients less than 1 month of age due to the increased risk of hypernatremia or in pediatric patients with metastatic cancers.
- Hypernatremia occurred in 12% to 26% of patients in clinical trials, including a single Grade 3 case. Hypokalemia occurred in 15% to 27% of patients in clinical trials, with Grade 3 or 4 occurring in 9% to 27% of patients. Monitor serum sodium and potassium at baseline and as clinically indicated. Withhold PEDMARK in patients with baseline serum sodium greater than 145 mmol/L.
- Monitor for signs and symptoms of hypernatremia and hypokalemia more closely if the glomerular filtration rate (GFR) falls below 60 mL/min/1.73 m².
- Administer antiemetics prior to each PEDMARK administration. Provide additional antiemetics and supportive care as appropriate.
- The most common adverse reactions (≥25% with difference between arms of >5% compared to cisplatin alone) in SIOPEL6 were vomiting, nausea, decreased hemoglobin, and hypernatremia. The most common adverse reaction (≥25% with difference between arms of >5% compared to cisplatin alone) in COG ACCL0431 was hypokalemia.

Please see full [Prescribing Information](#), including Patient Product Information, or go to [PEDMARKhcp.com](https://www.pedmarkhcp.com).

References:

1. PEDMARK [package insert]. Fennec Pharmaceuticals, Inc. 2. Landier W. Ototoxicity and cancer therapy. *Cancer*. 2016;122(11):1647-1658. 3. Hennegan K, Silber A, Dehipawala S, et al. Evaluating the burden of survival of platinum-induced hearing loss in pediatric solid-tumor patients: a systematic literature review. Poster PIH67 presented at: ISPOR Annual Meeting; May 18-20, 2020; Virtual. 4. American Hospital Formulary Service. AHFS Clinical Drug Information. February 27, 2023: 1. 5. Merative Micromedex DrugDex. Sodium Thiosulfate: DrugPoint Summary. August 20, 2025: 1-2. 7. 6. Wolters Kluwer UpToDate Lexidrug. Sodium Thiosulfate: Lexi-Drugs. October 28, 2025: 3. 7. Elsevier Clinical Pharmacology powered by ClinicalKey. Sodium Thiosulfate (All Populations Monograph). November 13, 2025: 2. 8. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Adolescent and Young Adult (AYA) Oncology Version 1.2026. © National Comprehensive Cancer Network, Inc. 2025. All rights reserved. Accessed August 13, 2025. To view the most recent and complete version of the guideline, go online to NCCN.org.

