

There is only one



PEDMARK is the first and only FDA-approved STS injection for cisplatin-induced ototoxicity¹

- Ready to administer—no mixing required
- There is no generic version of PEDMARK on the market, according to the PEDMARK Prescribing Information
- PEDMARK is not substitutable with other STS products

Recommended for the Adolescent and Young Adult 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 preventative treatment option to reduce CIO in pediatric/AYA patients with localized, nonmetastatic solid tumors.²

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

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CIO=cisplatin-induced ototoxicity; NCCN=National Comprehensive Cancer Network.

There is no substitute for FDA approval

- Product and administration protocols were approved together to support efficacious and safe delivery of STS for pediatric patients 1 month of age or older with solid tumors¹
- PEDMARK dosing, including dose modifications for younger and lower-weight patients, are specific to the PEDMARK formulation¹

FDA=Food and Drug Administration.

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.

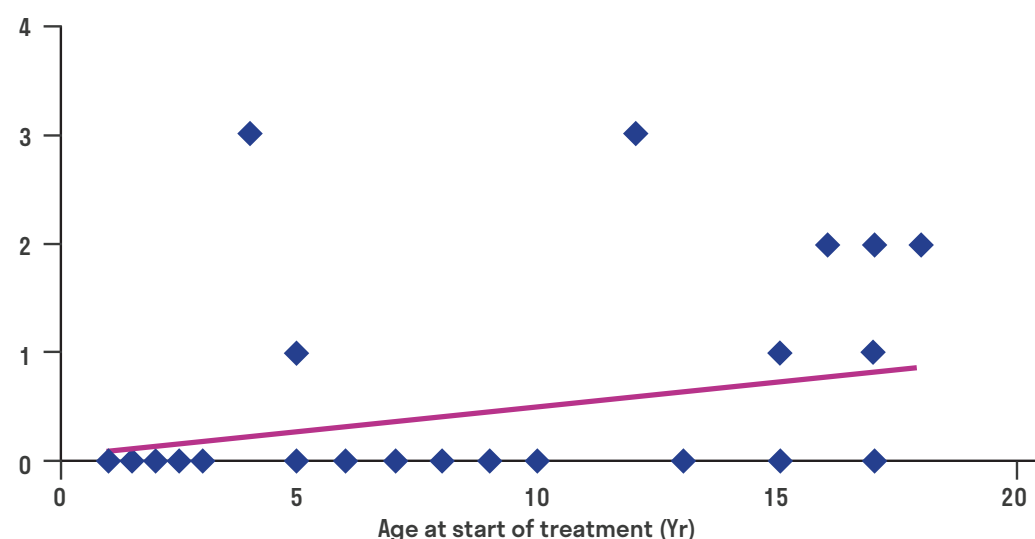
Please see additional Important Safety Information throughout. Please read the accompanying full Prescribing Information, including Patient Product Information in pocket, or go to PEDMARK.com.

Helping Them Hear Their Future Is Our Mission

About 50% of young adult cancer survivors experience the lifelong consequences of treatment-related hearing loss^{3,4}

- Associated with isolation and exclusion in social, professional, and academic settings
- Lack of knowledge about hearing loss as a late effect of treatment creates a disconnect—only 72% of those at risk receive hearing tests during follow-up
- Hearing loss is ignored or deprioritized as it is a “reminder” of the cancer

Older age at treatment start was associated with significantly more hearing loss⁵



- Other contributing factors to hearing loss included more time between treatment end and last audiometry, and use of ototoxic antibiotics⁵
- Overall, 25% of study participants experienced hearing loss of Brock Grade > 1, with hearing loss progressing over time⁵
 - Percentage of hearing loss associated with cisplatin was 62.5% in a cross-sectional study of 64 cancer survivors under 18 years of age⁵
- Other studies have shown that 11% of patients have hearing loss Grade ≥ 2 at 2 years post-treatment, growing to 44% of patients after more than 2 years⁵

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.

Audiologic Evaluations Are Key

CIO is associated with both cumulative cisplatin dose and dosing intensity^{5,6}

- In a cross-sectional study of 64 cancer survivors under 18 years of age, the risk for CIO-related hearing loss increased by 10% to 20% for every 100 mg/m² of cumulative cisplatin dose delivered
- Cisplatin dose per day and dose per cycle were associated with additive risk
- 8 out of 10 patients in another study developed hearing loss at a cumulative cisplatin dose >400 mg⁵

NCCN-recommended audiologic screening: adolescent and young adult survivors²

- High-risk population includes those receiving cisplatin ≥360 mg/m², carboplatin conditioning for HCT, radiation ≥30 Gy to the ear, and combination cisplatin/cranial or ear radiation
- Audiology testing is recommended as a post-therapy baseline and then every 5 years
- Cancer survivors with hearing impairment should also receive psychoeducational evaluation and support for educational, psychological, and social functioning

Expert recommendations for ototoxicity surveillance⁴

Expert recommendations for ototoxicity surveillance ⁴	
Surveillance Modality	<ul style="list-style-type: none"> • Pure-tone audiometry 1000-8000 Hz for survivors ≥6 years of age • High-frequency (>800 Hz) when available
Screening Schedule	<ul style="list-style-type: none"> • Start no later than end of treatment • Annual testing <6 years • Every other year 6-12 years • Every 5 years adolescents and young adults

Gy=Gray; HCT=hematopoietic cell transplantation; Hz=hertz.

Important Safety Information (continued)

- 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 SIOPEL 6 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.



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NCCN
RECOMMENDED

NCCN Guidelines for Adolescent and Young Adult (AYA) Oncology recommends sodium thiosulfate (PEDMARK) as a preventative treatment option to reduce CIO in pediatric/AYA patients with localized, nonmetastatic solid tumors.²



To learn more about PEDMARK, visit pedmarkhcp.com

References: 1. PEDMARK [package insert]. Hoboken, NJ: Fenneo Pharmaceuticals, Inc.; September 2022. 2. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Adolescent and Young Adult Oncology V.2.2024. © National Comprehensive Cancer Network, Inc. 2023. All rights reserved. Accessed October 11, 2023. To view the most recent and complete version of the guideline, go online to NCCN.org. 3. Khan A, Nidha Mubdi N, Budnick A, et al. The experience of hearing loss in adult survivors of childhood and young adult cancer: A qualitative study. *Cancer*. 2020;126(8):1776-1783. 4. Clemens E, Heuvel-Eibrink MM, Mulder RL, et al. Recommendations for ototoxicity surveillance for childhood, adolescent, and young adult cancer survivors: a report from the International Late effects of Childhood Cancer Guideline Harmonization Group in collaboration with the PanCare. *Lancet Oncol*. 2019;20(1):e29-e41. 5. Sherief LM, Rifky E, Attia M, et al. Platinum-induced ototoxicity in pediatric cancer survivors: GSTP1 c.313A>G variant association. *Medicine (Baltimore)*. 2022;101(45):e31627. 6. Moke DJ, Luo C, Millstein J, et al. Prevalence and risk factors for cisplatin-induced hearing loss in children, adolescents, and young adults: a multi-institutional North American cohort study. *Lancet Child Adolesc Health*. 2021;5(4):274-283.



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