

The first and only FDA-approved therapy to reduce the risk of cisplatin-induced ototoxicity¹

Effective April 1, 2024, use the following HCPCS code when prescribing PEDMARK²:

J0208

Injection, sodium thiosulfate (PEDMARK) 100 mg

REMINDER: Be sure to choose the PEDMARK-specific J-code every time.

Plan for PEDMARK Dosage and Administration Guide

- Dosage is calculated based on the patient's body weight
- Ready to administer—no mixing required
- **PEDMARK is not substitutable with other sodium thiosulfate products**

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.

Important Safety Information

- PEDMARK is contraindicated in patients with history of a severe hypersensitivity to sodium thiosulfate or any of its components.

FDA=Food & Drug Administration; HCPCS=Healthcare Common Procedure Coding System.

Please see additional Important Safety Information throughout and on page 7, and full Prescribing Information, including Patient Product Information, or go to [PEDMARK.com](https://www.pedmark.com).

Planning for PEDMARK¹

There are timing considerations when administering PEDMARK to minimize potential interference with cisplatin antitumor activity.

Before



1. Confirm a patient's cisplatin infusion lasted **no longer than 6 hours**.¹



2. Wait **6 hours after cisplatin infusion** to administer PEDMARK.¹



3. Ensure the patient's serum sodium level is **within normal range**.¹



4. Administer antiemetics **30 to 60 minutes prior to PEDMARK**, as needed.^{1,3,4}

During



5. Begin the infusion, and administer **over 15 minutes**.¹

After



6. Wait at least **10 hours after administering PEDMARK** before giving another cisplatin infusion.¹

Important Safety Information

• 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.

5-HT₃=5-hydroxytryptamine; NCCN=National Comprehensive Cancer Network® (NCCN®); NK-1=neurokinin-1.

Please see additional Important Safety Information throughout and on page 7, and full Prescribing Information, including Patient Product Information, or go to PEDMARK.com.

Recommended for patients who will receive emetogenic anticancer agents by the National Comprehensive Cancer Network® (NCCN®)

These recommendations are not consistent with the FDA indication. Always refer to the sodium thiosulfate injection (PEDMARK®) Prescribing Information and Instructions for Use.

**NCCN
RECOMMENDED**

NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Antiemesis recommends a prophylactic antiemetic regimen for patients receiving emetogenic anticancer agents (per institutional/clinician preferences).⁵

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

PEDMARK-associated nausea and vomiting are transient and manageable³

- It is recommended to administer an antiemetic 30 to 60 minutes prior to PEDMARK administration^{1,3,4}
- In clinical studies, only 2 patients discontinued PEDMARK due to nausea and vomiting (n=112)¹
- All grades of nausea (40%) and vomiting (85%) were seen in patients on PEDMARK and cisplatin¹
 - Grade 3 or 4 nausea was reported in 3.8% to 8% of clinical study participants
 - Grade 3 or 4 vomiting was reported in 7% to 8% of clinical study participants
- Other guideline-recommended antiemetic agents include NK-1 receptor antagonist, 5-HT₃ receptor antagonists, olanzapine, and/or dexamethasone⁵
- Treatment should be individualized based on patient characteristics and clinician experience⁵

Other considerations¹

- For patients who experience a hypersensitivity reaction, administer antihistamines and glucocorticoids (if appropriate) before each subsequent PEDMARK infusion
- PEDMARK is contraindicated in patients with a history of severe hypersensitivity to sodium thiosulfate or to its components

Administering PEDMARK® (sodium thiosulfate injection)

Preparation¹

- Calculate the dose (grams) and determine the number of vial(s) needed
- Visually inspect the contents of each single-dose vial for particulate matter and discoloration. Discard any vial with visible particulates or discoloration
- Withdraw the calculated dose from the vial(s) into a syringe or transfer the calculated dose into an **empty infusion bag**
 - **Use immediately** after withdrawing into a syringe or transferring to an empty infusion bag
 - If not used immediately, PEDMARK can be **stored in an infusion bag for no more than 18 hours** at 20°C to 22°C (68°F to 72°F). Discard unused portion
 - **No incompatibilities have been observed** between PEDMARK and infusion bags made of polyvinyl chloride, ethylene vinyl acetate, or polyolephin

Administration¹

- PEDMARK infusion should be administered **over 15 minutes**, following cisplatin infusions that are 1 to 6 hours in duration
- Administer PEDMARK **6 hours after** completion of a cisplatin infusion
- For multiday cisplatin regimens, administer PEDMARK 6 hours after completion of each cisplatin infusion and **at least 10 hours before** the next cisplatin infusion
- **Do not administer PEDMARK if the next cisplatin infusion is scheduled to begin in less than 10 hours**

Important Safety Information

- 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.

Please see additional Important Safety Information throughout and on page 7, and full Prescribing Information, including Patient Product Information, or go to PEDMARK.com.

Calculating the dosage¹

- Dosage is calculated based on the patient's actual body weight and body surface area; this will determine the number of 12.5 g/100 mL single-dose vials to use

Actual Body Weight	PEDMARK Dose
Less than 5 kg	10 g/m ²
5 to 10 kg	15 g/m ²
Greater than 10 kg	20 g/m ²

- PEDMARK is provided ready to use, with no dilution required
- **PEDMARK is not substitutable with other sodium thiosulfate products**
- Ensure serum sodium level is within normal range prior to initiating PEDMARK

Dose Modifications for Adverse Reactions¹

Adverse Reaction	Severity	Dosage Modification
Hypersensitivity	Grade 3 or 4	Permanently discontinue PEDMARK.
Hypernatremia	>145 mmol/L	Withhold PEDMARK until sodium is within normal limits. Resume at the same dose.
Hypokalemia	Grade 3 or 4	Withhold PEDMARK until potassium is within normal limits. Resume at the same dose.
Other Adverse Reactions	Grade 3	Withhold until ≤Grade 1. Resume at the same dose.
	Grade 4	Permanently discontinue PEDMARK.



Our commitment to you, your patients, and their families

Hearing education, access, and reimbursement support, including:

- **In-home nursing support:** PEDMARK administration by licensed nurses nationwide
- **Insurance-related support:** Benefits investigation, prior authorization, and/or appeal process
- **Patient Assistance Program:** Provides eligible patients with access to free product in accordance with the physician's on-label prescribing decision
- **Quick Start Program:** New patients experiencing delays in determining coverage approval may receive a free, limited supply of PEDMARK
- **Bridge Program:** Existing patients experiencing insurance coverage interruptions may receive a free, limited supply of PEDMARK

To learn more about the FENNEC HEARS™ program, call (855-615-7946) or visit [PEDMARK.com/fennec-hears](https://pedmark.com/fennec-hears).

References: 1. PEDMARK [package insert]. Hoboken, NJ: Fennec Pharmaceuticals, Inc.; October 2023. 2. Centers for Medicare & Medicaid Services. Centers for Medicare & Medicaid Services (CMS) Healthcare Common Procedure Coding System (HCPCS) Application Summaries and Coding Recommendations. Fourth Quarter, 2023 HCPCS Coding Cycle. Accessed February 2, 2024. <https://www.cms.gov/files/document/2023-hcpcs-application-summary-quarter-4-2023-drugs-and-biologics-updated-1/30/2024.pdf> 3. Data on file, Fennec Pharmaceuticals, Inc. 4. Karthaus M, Schiel X, Ruhlmann CH, Celio L. Neurokinin-1 receptor antagonists: review of their role for the prevention of chemotherapy-induced nausea and vomiting in adults. *Expert Rev Clin Pharmacol*. 2019 Jul;12(7):661-680. doi: 10.1080/17512433.2019.1621162. Epub 2019 Jun 13. PMID: 31194593. 5. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Antiemesis V.1.2024. © National Comprehensive Cancer Network, Inc. 2023. All rights reserved. Accessed January 25, 2024. To view the most recent and complete version of the guideline, go online to [NCCN.org](https://www.nccn.org).

Please read the accompanying full Prescribing Information, including Patient Product Information or go to [PEDMARK.com](https://pedmark.com).

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.

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/1.73m².
- 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.

COG=Children's Oncology Group; SIOPEL=International Childhood Liver Tumor Strategy Group.

Overview

Efficacy¹

- The efficacy of PEDMARK in reducing the risk of cisplatin-associated ototoxicity was evaluated in 2 multicenter studies: SIOPEL 6 and COG ACCL0431; in each study, the incidence of hearing loss was lower in the PEDMARK + cisplatin arm compared with the cisplatin alone arm²
- For details about the designs and findings of PEDMARK clinical trials, please see Section 14 of the Full Prescribing Information

Dosing & Administration^{1,3}

- Dosage is calculated based on the patient's actual body weight
- Ready to administer—no mixing required
- Administer antiemetics **30 to 60 minutes** prior to PEDMARK as needed
- PEDMARK infusion should be administered **over 15 minutes**, following cisplatin infusions that are 1 to 6 hours in duration
- Administer PEDMARK **6 hours after** completion of a cisplatin infusion
- Do not administer PEDMARK if the next cisplatin infusion is scheduled to begin in **less than 10 hours**

How Supplied & Storage¹

- PEDMARK is a clear, colorless, sterile solution in a single-dose vial containing 12.5 g/100 mL (125 mg/mL)
- Store at 20°C to 25°C (68°F to 77°F); excursions are permitted between 15°C and 30°C (59°F to 86°F)

Important Safety Information

- Hyponatremia 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.



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