

## Thank goodness for



Children who get platinum-based chemotherapy, such as cisplatin, are at risk for permanent hearing loss. PEDMARK may help protect their hearing.

# What is cisplatin-induced hearing loss?

Cisplatin is a powerful medicine used to treat cancer in children. Over time, cisplatin builds up in the cochlea (cok-lee-ah). The cochlea is the spiral-shaped part of the inner ear. Thousands of tiny hair cells in the cochlea work to make sound louder. Cisplatin damages these hair cells, which cannot grow back. The result may be permanent hearing loss in both ears.



Please see pages 4 to 6 for Important Safety Information, and click for full <u>Prescribing Information</u>.

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# A lifetime of hearing loss can start with the first cisplatin cycle

Cochlear damage can begin early and continue even after cisplatin treatment ends. You may not even notice it at first. In the early stages, you may think your child simply isn't paying attention to things around them. In reality, they may not hear higher-pitched sounds like music or birds. Later, they may not hear lower-pitched sounds like thunder. That's why it's important to get your child's hearing tested before, during, and after treatment.

# Hearing loss impacts your child in many different ways

#### Affects the ability to hear different sounds



#### What is PEDMARK?

- PEDMARK is a prescription medicine used to decrease the risk of hearing loss in children 1 month of age and older who are receiving cisplatin for solid tumors (cancer) that have not spread to other parts of the body.
- It is not known if PEDMARK is safe and effective when given after cisplatin infusions longer than 6 hours. It is not known if PEDMARK is safe and effective in children less than 1 month of age.
   PEDMARK is not recommended in children younger than 1 month of age, or in children whose cancer has spread to other parts of the body.

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## PEDMARK protection helps children hear their futures

PEDMARK is the first and only Food & Drug Administration (FDA)-approved treatment specifically designed to protect your child's ears after cisplatin treatment.

It isn't known exactly how PEDMARK works, but scientists think it may:

- Help the body make antioxidants that fight the toxic build-up caused by cisplatin
- Neutralize the toxins made by cisplatin molecules
- Attach to the cisplatin molecules to reduce the amount of toxins they release

#### **Important Safety Information**

- Do not allow your child to receive PEDMARK if they have had a severe allergic reaction to sodium thiosulfate or any of the other ingredients in PEDMARK.
- Allergic reactions can happen with PEDMARK and can be serious and life-threatening. Your health care provider will monitor your child for allergic reactions during the PEDMARK infusion. Your healthcare provider will stop the infusion and provide treatment if your child has an allergic reaction. If your child has an allergic reaction, your healthcare provider will give your child certain medicines before each PEDMARK infusion. Tell your healthcare provider right away if your child has any of these signs of an allergic reaction: rash, hives (raised bumps), chest tightness, wheezing, trouble breathing, swelling of the face, lips, tongue, or throat.

### **Timing is everything**

PEDMARK is given intravenously and takes about 15 minutes. Your child will get PEDMARK 6 hours after the end of their 1- to 6-hour cisplatin treatment. The timing is important because:

- If PEDMARK is given too soon, it may reduce the effectiveness of the cisplatin
- If PEDMARK is given more than 6 hours after cisplatin, it may not work to help protect your child's hearing



PEDMARK should not be given if your child is scheduled to start their next cisplatin infusion in less than 10 hours.

#### **Important Safety Information**

- Changes in salt and potassium levels in the blood are common with PEDMARK but can also be serious. Your healthcare provider will do blood tests to check your child's sodium and potassium levels before starting and as needed during treatment with PEDMARK. Tell your healthcare provider right away if your child develops any of the following signs or symptoms: feeling tired or weak, feeling restless, muscle weakness, seizures.
- Nausea and vomiting are common with PEDMARK but can also be serious. Your healthcare provider will give your child medicines before each PEDMARK infusion to help prevent nausea and vomiting.



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# PEDMARK was studied in children around the world

PEDMARK showed that it could help protect children's ears after cisplatin treatment in 2 different studies.

Study	Cisplatin + PEDMARK	Cisplatin Only
International Child Liver Tumor Strategy Group (SIOPEL)	<b>39%</b> hearing loss	68% hearing loss
Children's Oncology Group (COG)	44% hearing loss	58% hearing loss

Scientists measured hearing loss using pure-tone audiometry. This is a hearing test that shows the softest sound a person can hear at least 50% of the time.

#### Scientists also looked at PEDMARK safety

Only 1 child in each study stopped using PEDMARK due to side effects. The most commonly reported side effect was decreased red blood cells.

#### **Important Safety Information**

- The most common side effects of PEDMARK include decreased red blood cells (anemia).
- These are not all the possible side effects of PEDMARK. Call your child's doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088. You may also report side effects to Fennec Pharmaceuticals, Inc. at 1-833-336-6321.



### Your source for access support

At Fennec, we don't want cost to stand in the way of your child getting PEDMARK. That's why we created Fennec HEARS. It's your single source program for both patient financial and product access support.

#### **Affording PEDMARK**

- If you have commercial or private health insurance: You may be eligible for a \$0 copay savings program
- If you have Medicaid (government insurance):
   Copay assistance may be available through independent charities
- If you are uninsured: The Fennec Patient
   Assistance Program is committed to providing access to PEDMARK to eligible patients without insurance coverage

#### **Our Care Coordinators get you started**

Once your doctor has prescribed PEDMARK, they can:

- Answer insurance questions about coverage for PEDMARK
- Provide you with tips and resources for managing your child's treatment

Contact a Fennec HEARS Care Coordinator at 1-833-7PEDMARK (1-833-773-3627) from 9 AM to 6 PM, ET, Monday through Friday or visit our <u>website</u>.



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### Frequently asked questions

How is PEDMARK given?

How does PEDMARK work?

How old does my child have to be to get PEDMARK?

What kind of chemotherapy does my child need to be on to get PEDMARK?

How long do we have to wait after chemotherapy to get PEDMARK?

What happens if my child is getting a second chemotherapy treatment within 24 hours?

#### **Explore helpful tools and resources**

To find out more about PEDMARK, visit us at pedmark.com.

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