

Patient Information
PEDMARK® (ped-mark)
(sodium thiosulfate injection)
for intravenous use

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.

Who should not receive PEDMARK?

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. See the end of this leaflet for a complete list of ingredients in PEDMARK.

Before receiving PEDMARK, tell your healthcare provider about all of your child's medical conditions, including if your child:

- is allergic to sulfites
- has asthma
- has kidney problems
- is on a low salt diet
- is pregnant or plans to become pregnant. It is not known if PEDMARK will harm the unborn baby.
- is breastfeeding or plans to breastfeed. It is not known if PEDMARK passes into the breastmilk.

You should also read the cisplatin Prescribing Information for important pregnancy and breastfeeding information.

Tell your healthcare provider about all the medicines your child takes, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Know the medicines your child takes. Keep a list of them to show to your healthcare provider or pharmacist when your child gets a new medicine.

How will your child receive PEDMARK?

- PEDMARK will be given to your child as an intravenous (IV) infusion into a vein, usually over 15 minutes.
- PEDMARK is given 6 hours after the end of a cisplatin treatment. Your healthcare provider may decide not to treat your child with PEDMARK if it is too soon before the next cisplatin treatment.
- Your healthcare provider may temporarily stop or completely stop your child's treatment with PEDMARK if your child develops certain side effects.

What are the possible side effects of PEDMARK?

PEDMARK may cause serious side effects, including:

- **Allergic reactions.** Allergic reactions can happen with PEDMARK and can be serious and life-threatening. Your healthcare 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 develops 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

- **Increased salt (sodium) and decreased potassium levels in the blood.** Changes in these levels 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.** 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.

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 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.

General information about the safe and effective use of PEDMARK.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. You can ask your pharmacist or healthcare provider for information about PEDMARK that is written for health professionals.

What are the ingredients in PEDMARK?

Active ingredient: sodium thiosulfate anhydrous

Inactive ingredients: boric acid. Sodium hydroxide and hydrochloric acid may have been used for pH adjustment.

Distributed by Fennec Pharmaceuticals, Inc., 221 River Street, Hoboken, NJ 07030

PEDMARK is a registered trademark of Fennec Pharmaceuticals, Inc.

For more information, go to www.fennecpharma.com or call 1-833-336-6321.

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This Patient Information has been approved by the U.S. Food and Drug Administration

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