Package leaflet: Information for the patient

Pedmarqsi 80 mg/mL solution for infusion
sodium thiosulfate

Read all of this leaflet carefully before you or your child starts receiving this medicine because it contains important information.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask the doctor or nurse.
- If you or your child get any side effects, talk to the doctor or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Pedmarqsi is and what it is used for

Pedmarqsi contains the active substance sodium thiosulfate.

Pedmarqsi is used to reduce the risk of hearing loss from the cancer medicine cisplatin. It is given to children and adolescents aged 1 month to 18 years who are being treated with cisplatin for solid tumours that have not spread to other areas of the body.

2. What you need to know before you or your child receives Pedmarqsi

Do not give Pedmarqsi
if the child is:
- allergic to sodium thiosulfate or any of the other ingredients of this medicine (listed in section 6)
- a baby under the age of 1 month

Warnings and precautions
Talk to a doctor or nurse before you or your child receives Pedmarqsi if the child:
- has had an allergic reaction like a rash, hives or difficulty breathing after a previous dose of sodium thiosulfate
- has a known allergy to chemicals called sulfites − this may mean you or the child is more likely to have an allergic reaction to this medicine
- has poor kidney function or serious kidney disease
- needs a low salt diet because of another medical condition

Other medicines and Pedmarqsi
Tell the doctor or nurse if you or your child is taking, has recently taken or might take any other medicines.

Pregnancy and breast-feeding

This medicine should not be given if you or your child is pregnant (or could be pregnant), or is breast-feeding. This medicine is only given after cisplatin chemotherapy and cisplatin can harm your baby. Discuss with your doctor whether there is a need for contraception both during treatment and for 6 months after treatment.

Pedmarqsi contains boric acid
This medicine contains boric acid which may impair fertility when given chronically.

Pedmarqsi contains sodium
This medicine contains 23 mg sodium (main component of cooking/table salt) in each mL. This is equivalent to 1-2% of the safe dietary intake of sodium for children aged 1 to 17 years and 12% in babies aged 7 to 11 months.

3. How Pedmarqsi is given

Before you or your child will receive this medicine, he/she will be given anti-sickness medicines to help prevent vomiting.

This medicine is a solution that is given as an infusion (drip) into a vein by a doctor or nurse. This is usually done via a tube inserted into a vein in the chest, known as a central line. The infusion is given over 15 minutes. Treatment is started 6 hours after the dose of cisplatin has finished.

The dose of this medicine is worked out based on your size (body surface area) in m^2, which is calculated from height and weight. The recommended dose for those weighing 10 kg or more is 12.8 g per m^2; lower doses are given to those weighing less than 10 kg. Your doctor will work out the dose that is right for you or your child.

If you or your child receives more Pedmarqsi than he/she should
Because the dose is worked out and checked by healthcare professionals, it is unlikely that you or your child will be given the wrong amount. In case of overdose, you or your child may experience nausea, vomiting, changes to levels of sodium, phosphate or potassium in the blood, changes to blood pressure, or acidic blood (metabolic acidosis) which can cause nausea, vomiting, drowsiness and breathlessness. Your doctor may give you or your child symptomatic treatment for these side effects.

If you have any further questions on the use of this medicine, ask the doctor or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Serious side effects

If you or your child has a severe allergic reaction to this medicine with symptoms such as a skin rash, tight chest, wheezing, shortness of breath or feeling cold you or they should tell a doctor or nurse immediately.

Other side effects

The other side effects seen with this medicine are usually mild. The side effects you or your child may experience are:

Very common (may affect more than 1 in 10 people)
- Feeling sick (nausea)
- Vomiting
- Reduced level of phosphate or potassium seen in blood tests

- Increased level of sodium seen in blood tests

Common (may affect more than 1 in 100 people)
- Increased or reduced blood pressure
- Reduced level of calcium seen in blood tests
- Acidic blood (metabolic acidosis) which can cause nausea, vomiting, drowsiness and breathlessness

Reporting of side effects
If you or your child get any side effects, talk to the doctor or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via Yellow Card Scheme, Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Pedmarqsi

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the vial after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Pedmarqsi contains
- The active substance is sodium thiosulfate, in anhydrous form.
- The other ingredients are:
  - boric acid (0.25 mg/mL)
  - water for injections
  - hydrochloric acid and sodium hydroxide for pH adjustment (see section 2; Pedmarqsi contains sodium).

What Pedmarqsi looks like and contents of the pack
This medicine is a solution for infusion.
This medicine is a clear and colourless sterile solution supplied in clear glass vials sealed with a rubber stopper and an aluminium flip-off overseal. Each carton contains one vial.

Marketing Authorisation Holder
Norgine Pharmaceuticals Limited
Norgine House, Widewater Place
Moorhall Road, Harefield
Uxbridge, UB9 6NS
United Kingdom

Manufacturer
Norgine B.V
Antonio Vivaldistraat 150
1083 HP Amsterdam
Netherlands

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The following information is intended **for healthcare professionals only**:

Posology and method of administration

Time of administration in relation to cisplatin

The timing of sodium thiosulfate administration relative to cisplatin chemotherapy is critical.
If sodium thiosulfate is administered:

- Less than 6 hours after end of cisplatin infusion: may reduce cisplatin efficacy against the tumour
- More than 6 hours after end of cisplatin infusion: may not be effective in preventing ototoxicity.

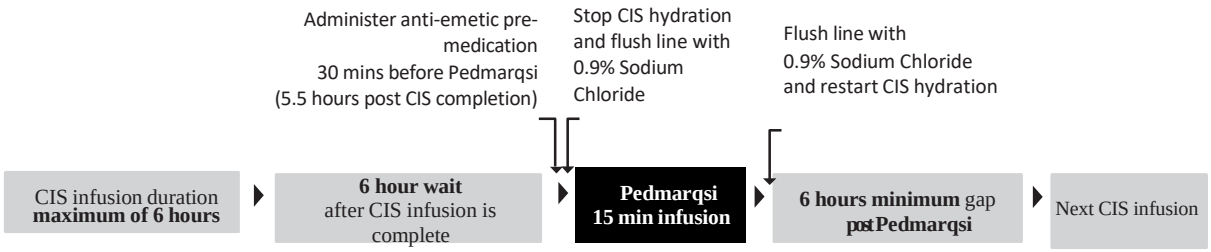
Only use sodium thiosulfate following cisplatin infusion duration of 6 hours or less. Do not use sodium thiosulfate if:

- Cisplatin infusion exceeds 6 hours, or
- A subsequent cisplatin infusion is planned within 6 hours.

When cisplatin is administered on consecutive days, ensure a minimum 6-hour gap after sodium thiosulfate infusion before a subsequent cisplatin infusion is given.

After end of cisplatin infusion:

- Provide highly effective multi-agent intravenous antiemetic therapy 30 minutes prior to administration of sodium thiosulfate i.e. 5.5 hours after completion of cisplatin infusion
- This medicine is a ready to use solution for infusion
- Prepare the required mL of sodium thiosulfate, 80 mg/mL, in a syringe or add to an empty, sterile infusion bag
- Stop cisplatin hydration fluid and flush line with sodium chloride 0.9%
- Infuse sodium thiosulfate over 15 minutes (6 hours after completion of cisplatin infusion)
- Flush line with sodium chloride 0.9% and restart the cisplatin hydration immediately afterwards



CIS = cisplatin

See '*Time of administration in relation to cisplatin*' for critical information regarding timing of sodium thiosulfate administration.

This medicine is provided as a single use vial containing 8 g as 80 mg/mL. The recommended dose of sodium thiosulfate for the prevention of cisplatin-induced ototoxicity is weight based and normalised to body surface area according to the table below:

Body Weight	Dose	Volume
> 10 kg	12.8 g/m^2	160 mL/m^2
5 to 10 kg	9.6 g/m^2	120 mL/m^2
< 5 kg	6.4 g/m^2	80 mL/m^2

Instructions for use and handling, and disposal

This medicine is intended only for single use. Any unused portion of the solution should be disposed of in accordance with the local requirements.

Chemical and physical in-use stability has been demonstrated for 24 hours at controlled room temperature for product stored in polyvinyl chloride, ethylene vinyl acetate and polyolephine intravenous bags.

From a microbial point of view, the product should be used immediately after opening. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2 to 8ºC.