



Important Information Direct Healthcare Professional Communication

28th October 2026

PEDMARQSI (sodium thiosulfate) 80 mg/mL solution for infusion: requirement to visually inspect each vial before administration and mandatory use of an in-line filter

Dear Healthcare Professional,

Norgine BV, in agreement with the European Medicines Agency and Health Products Regulatory Authority (HPRA) would like to inform you of the following:

Summary

- Each vial must be visually inspected before administration, as described in section 4.2 of the summary of product characteristics¹. Do not use any vial in which particles or discolouration are observed.
- As an additional precaution, vials should be visually inspected for particulate matter and discolouration upon receipt.
- An appropriate in-line filter (a filter placed in the infusion line to help prevent particles from reaching the patient) must be used during administration with PEDMARQSI. This does not replace the requirement to visually inspect vials before use.

1. *PEDMARQSI (sodium thiosulfate) 80 mg/mL Solution for Infusion. Summary of Product Characteristics (SmPC), current approved version.* <https://www.ema.europa.eu/en/medicines/human/EPAR/pedmarqsi>

2. European Pharmacopoeia 11th Edition, Chapter 2.9.20, Particulate Contamination: Visible Particles.



Background on the safety concern

PEDMARQSI is indicated for the prevention of ototoxicity induced by cisplatin chemotherapy in patients 1 month to <18 years of age with localised, non-metastatic, solid tumours.

Visible particulate matter was identified during evaluation of retained samples from two bulk batches of PEDMARQSI. Finished-product batches manufactured from these batches have been recalled at hospital pharmacy level. Other batches of PEDMARQSI remain available for use.

The particles identified were approximately 80–600 µm in size. The potential clinical consequences of such particulate matter are embolic, thrombotic or infusion-site reactions; to date, no events suggestive of these risks, have been reported. Sterility remains unaffected, and the visible particulate matter does not present a risk of infection.

The reported adverse events are consistent with the known safety profile of PEDMARQSI described in the summary of product characteristics, predominantly nausea, vomiting, hypersensitivity and electrolyte disturbances. No new safety signal has been identified.

The root cause investigation is ongoing and release of further batches has been suspended pending its outcome.

Visual inspection before administration

For the visual inspections it is recommended that before use the vial is gently swirled or inverted without introducing air bubbles and inspected against both a black and a white background under good lighting². Do not use the vial if any particles or discolouration are observed.

In-line filters

An in-line filter must be used during administration of PEDMARQSI as an additional precaution to minimise the risk of particulate matter being administered to the patient. The use of an in-line filter does not replace the requirement for visual inspection, and any vial containing visible particles or showing discolouration must not be used.

The selection of an appropriate filter should be determined by the healthcare professional based on their clinical judgement and applicable local clinical practice.

1. PEDMARQSI (sodium thiosulfate) 80 mg/mL Solution for Infusion. Summary of Product Characteristics (SmPC), current approved version. <https://www.ema.europa.eu/en/medicines/human/EPAR/pedmarqsi>
2. European Pharmacopoeia 11th Edition, Chapter 2.9.20, Particulate Contamination: Visible Particles.

**Call for reporting**

Healthcare professionals are asked to report any suspected adverse reactions or product defects, such as particulate matter or discolouration, including batch/lot number if available.

Adverse events should be reported to Norgine on [+441895826606](tel:+441895826606) or medinfo@norgine.com and to the HPRA (medsafety@hpra.ie).

Company contact point

For further information, contact Norgine by telephone on +441895 826 600, via email on ukisupport@norgine.com, or by post at ARC Uxbridge, Building 1, Sanderson Road, Uxbridge, UB8 1DH, United Kingdom.

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1. PEDMARQSI (sodium thiosulfate) 80 mg/mL Solution for Infusion. Summary of Product Characteristics (SmPC), current approved version. <https://www.ema.europa.eu/en/medicines/human/EPAR/pedmarqsi>
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