

Medicine Shortage Communication

<Date>

<Endoxan/Sendoxan/Genoxal> (cyclophosphamide, <100 mg / 200 mg / 500 mg / 1 g / 2 g> powder for solution for injection or infusion): supply shortage

Dear Healthcare Professional,

Baxter is notifying healthcare professionals about a shortage of intravenous Endoxan/Sendoxan/Genoxal (cyclophosphamide).

Overview of situation

- **A technical disruption at Baxter's contract manufacturing site led to an interruption in the manufacturing and product release for cyclophosphamide powder for solution for injection or infusion (<Endoxan/Sendoxan/Genoxal>, powder for solution for injection or infusion, <100 mg / 200 mg / 500 mg / 1 g / 2 g >).**
 - **This has led, or is expected to lead, to a shortage of the medicine in all EU countries. While the timing of supply interruptions will differ between countries, the supply shortage is expected to continue through Q3 2026.**
 - **Baxter is working with the manufacturing partner to restore normal supply as quickly as possible.**
 - **The supply of Baxter cyclophosphamide in tablet form is unaffected.**
 - **The shortage is not due to any safety, efficacy or quality concern with currently available supplies of cyclophosphamide.**
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Mitigation measures

In order to manage the shortage, Baxter is engaging with the European Medicines Agency and the National Competent Authority on mitigation measures.

During the shortage, healthcare professionals should:

- **confirm that there are adequate supplies of intravenous cyclophosphamide available to complete a treatment course before starting any new patients on treatment.**
- **be aware that Baxter is the primary supplier of cyclophosphamide in the EU, however, there are other suppliers of intravenous cyclophosphamide in many EU Member States.**
- **note that the supply of Baxter cyclophosphamide in tablet form is unaffected.**
- **consult EMA's shortage catalogue and country-specific shortage registers (where available) or your national competent authority for additional information on the shortage.**
- **advise concerned patients and caregivers to seek medical advice from their healthcare provider.**

Background on the shortage

Cyclophosphamide is used in clinical practice for the treatment of a broad range of haematologic malignancies and solid tumours, as well as in conditioning regimens for bone-marrow transplantation. It is also used in the management of certain severe autoimmune conditions.

Baxter's contract manufacturing organisation recently experienced a technical disruption that affected site operations, including production planning and inventory systems. At the same time, the site has been implementing corrective actions following a regulatory inspection. Together, these factors have led to a short-term interruption in manufacturing and product release for cyclophosphamide powder for solution for injection or infusion (<Endoxan/Sendoxan/Genoxal>).

Baxter, as the marketing authorisation holder, is working closely with the manufacturing partner to resolve the situation and restore supplies as quickly as possible. Manufacturing has now resumed at the facility.

While Baxter is a key supplier of cyclophosphamide across the EU, there are other marketing authorisation holders who can supply intravenous cyclophosphamide. The supply of Baxter cyclophosphamide in tablet form is unaffected.

Company contact point

Please contact Baxter's Medical Information service, details of which can be found on Baxter's country-specific websites.