



Safety Alert 004/24

Issue date
01 March 2024

Distributed to:

Chief Executives
Directors of Clinical Governance
Director, Regulation and Compliance Unit

Action required by:

Chief Executives
Directors of Clinical Governance

We recommend you also inform:

Directors, Managers and Staff of:

- Emergency Departments
- Intensive Care Units
- Surgical Departments
- Anaesthetics
- General Medicine
- Nursing and Midwifery Services
- Medical Services
- Pharmacy Services

Drug and Therapeutics Committees

Deadline for completion of action – ASAP

Content informed by:

ACI Anaesthesia Perioperative Care, Emergency Care, Intensive Care, Paediatrics, Pain Management, Surgical Care and Trauma and Injury Management Networks/Institutes.

Content reviewed by:

Medicines Shortage Assessment and Management team

Clinical Excellence Commission

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Review date
March 2025

UPDATED: Critical disruption to supply – Intravenous (IV) paracetamol solution for injection/infusion

What's new in this Safety Alert?

This Safety Alert **replaces SN:032/23 Disruption to supply – Intravenous (IV) paracetamol solution for injection** (now rescinded). This Safety Alert includes additional medication management strategies to ensure adequate management of supply throughout the period.

Situation

There is a **global disruption** to the supply of multiple brands of intravenous (IV) paracetamol solution for injection/infusion products due to a **raw material issue**. The disruption to supply is not expected to resolve until at least 30 June 2024, with the potential to extend until December 2024.

Background

IV paracetamol is a non-opioid analgesic and antipyretic agent that is indicated in the relief of mild to moderate pain and the reduction of fever when oral/rectal administration is not feasible or deemed inappropriate.

IV paracetamol is listed with restriction on the [NSW Medicines Formulary](#). Please refer to the individual listing for further information.

Assessment

In November 2023, NSW Health was notified of a disruption to the supply of IV paracetamol. Since initial notification, supply of IV paracetamol has been limited.

Due to a global shortage of raw materials, it is expected that there will be an ongoing disruption to the supply of multiple brands of IV paracetamol 1000 mg/100 mL solution for injection from March, which is not expected to resolve until at least 30 June 2024. There is potential for patient level impact in mid to late-March due to a complete disruption to supply. IV paracetamol 500 mg/50 mL is currently constrained and expected to be subject to disruption to supply in the near future. Oral and rectal paracetamol products remain unaffected.

At the time of publication, there are no alternatives approved for use under Section 19A of the *Therapeutic Goods Act 1989*. HealthShare NSW continue to investigate the availability of alternatives. If alternatives are to become available, this information will be published on the [TGA S19A approvals database](#).

Recommendations

- Drug and Therapeutics Committees (DTCs) must ensure that a process is in place to preserve remaining supplies of IV paracetamol.
- **Remaining stock of IV paracetamol solution for injection/infusion must be reserved for patients in whom oral, enteral, or rectal routes of administration are not appropriate. Regular review of IV paracetamol orders is to occur every 6 to 8 hours, with the view of de-escalating to an alternative dose form as soon as possible.**
- Clinicians are to consider the use of alternative routes of administration or alternative analgesic agents for the treatment of mild-moderate pain where clinically appropriate. Alternative agents may include non-steroidal anti-inflammatory drugs (NSAIDs). Advice may need to be sought from the local Acute Pain Specialist team.
- In accordance with the [Paracetamol Standard](#) of the NSW Health Policy Directive *High-Risk Medicines Management* (PD2024_006): Local Drug and Therapeutics Committees should review any local protocols and ensure the inclusion of any restrictions to limit use of intravenous paracetamol, in accordance with this Safety Alert.



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- A facility-wide review of stock holdings must be conducted with all locations holding stock identified.
 - All excess stock is to be retrieved from wards and clinics.
 - A reduction of minimum/maximum quantities held in imprest areas should be enacted to assist with stock management throughout the disruption to supply.
 - Individual patient dispensing should be considered where feasible.
- Ensure back orders based on average usage are placed with preferred wholesalers to ensure adequate distribution of stock when it becomes available.

Required actions for the Local Health Districts/Networks

1. **Immediately upon receipt**, distribute this Safety Alert to all relevant clinicians and clinical departments where IV paracetamol is held, prescribed, and/or administered, and include this Safety Alert in relevant handovers and safety huddles.
2. Undertake a local risk assessment and incorporate the above recommendations to manage the disruption of supply of IV paracetamol. Ensure a system is in place to document actions taken in response to this Safety Alert.
3. **Within 24 hours**, acknowledge receipt and distribution of this Safety Alert to:
CEC-MedicationSafety@health.nsw.gov.au