

# Risk of toxicity from 'colic preparations' containing belladonna

## SAFETY NOTICE 011/24

Issue Date:	7 June 2024
	Chief Executives; Directors of Clinical Governance; Director, Regulation and Compliance Unit
KEY MESSAGE:	Inform NSW Health clinicians of the risk of toxicity associated with 'colic preparations' containing belladonna and advise that a heightened degree of suspicion for belladonna toxicity is warranted when assessing neonates/infants presenting with symptoms of anticholinergic syndrome.
ACTION REQUIRED BY:	Chief Executives, Directors of Clinical Governance
REQUIRED ACTION:	<ol style="list-style-type: none"><li>1. Distribute this Safety Notice to all relevant clinicians and clinical departments where patients may present with symptoms of belladonna toxicity related to the use of 'colic preparations'.</li><li>2. Ensure that clinicians and other relevant staff are aware of the <i>Recommendations</i> of this Safety Notice and take appropriate action.</li><li>3. Confirm receipt and distribution of this Safety Notice within <b>72 hours</b> to: <u><a href="mailto:CEC-MedicationSafety@health.nsw.gov.au">CEC-MedicationSafety@health.nsw.gov.au</a></u>.</li></ol>
DEADLINE:	COB 12 June 2024
We recommend you also inform:	<p>Directors, Managers and Staff of:</p> <ul style="list-style-type: none"><li>• Emergency Departments</li><li>• Neonatal and Paediatric Units (including Paediatric Outpatient Departments)</li><li>• Child and Family Health Services</li><li>• Maternity Services</li><li>• Medical Services</li><li>• Pharmacy Departments</li><li>• Nursing/Midwifery Services</li><li>• Drug and Therapeutics Committees</li></ul> <p>All other relevant clinicians, departments and committees.</p>
Website:	<u><a href="https://www.health.nsw.gov.au/sabs/Pages/default.aspx">https://www.health.nsw.gov.au/sabs/Pages/default.aspx</a></u> <u><a href="http://internal.health.nsw.gov.au/quality/sabs/index.html">http://internal.health.nsw.gov.au/quality/sabs/index.html</a></u>
Review date:	June 2025

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### Situation

There have been ongoing reports of neonates/infants in the community presenting to GPs or hospital emergency departments with suspected anticholinergic syndrome, which may occur after administration of a 'colic preparation' purchased online that contains belladonna. Similar cases have also been reported in other jurisdictions.

This Safety Notice is to inform NSW Health clinicians of the risk of toxicity associated with 'colic preparations' containing belladonna and advise that a heightened degree of suspicion for belladonna toxicity is warranted when assessing neonates/infants presenting with symptoms of anticholinergic syndrome.

### Background

Belladonna is a plant that contains compounds that produce anticholinergic activity. Due to its anticholinergic properties, it is sometimes used as base for an ingredient in preparations which are marketed to treat symptoms of 'colic' in neonates/infants (see **note**). Reported cases of harm are related to use at both recommended doses, and after inadvertent dosing errors.

**Note:** 'Colic' is an out-dated term used to describe excessive crying in neonates/infants. There is no strong evidence that this is due to intestinal problems. Medication (e.g., anti-reflux or anticholinergic medicines), herbal remedies or other 'colic preparations' are not recommended as treatment for 'colic'.

### Assessment

Belladonna containing 'colic preparations' whether purchased from a registered Australian pharmacy, or other source, have the potential to cause patient harm associated with anticholinergic syndrome.

Clinicians are advised to have heightened suspicion for belladonna toxicity in neonates, infants and young children presenting with symptoms of anticholinergic syndrome where 'colic preparations' have been ingested.

Signs and symptoms of belladonna toxicity include: erythematous flushed skin, dry skin, dry mouth, dilated pupils, tachycardia, urinary retention, gastrointestinal ileus, raised temperature, agitation, drowsiness, floppiness, poor feeding and occasionally seizures.

Onset of toxicity is usually within 30 minutes to 4 hours however symptoms may be significantly delayed or prolonged due to decreased gastric motility and may vary due to frequent and repeated dosing.

## Recommendations

- ‘Colic preparations’ containing belladonna are **not recommended** to be given to neonates or infants.
- Any neonate or infant with sudden onset of irritability and crying should be assessed by a medical professional to exclude medical cause, and parents/carers should be provided with reassurance and education regarding crying and sleep patterns. Parents can be referred to Child and Family Health Services or their general practitioner for support.
- Exercise heightened awareness of the possibility of belladonna toxicity following ingestion of ‘colic preparations’. Ensure specific information regarding the formulation of ‘colic preparations’ is obtained during history taking including ingredients, brand, and recommended and administered dose.
- If anticholinergic syndrome is suspected, seek senior guidance and contact the NSW Poisons Information Centre (13 11 26) or a clinical toxicologist for specialist advice regarding diagnosis and management of patients presenting with symptoms of belladonna toxicity.
- Report any cases of suspected belladonna toxicity associated with ‘colic preparations’:
  - via the local incident management system (e.g., ims+)
  - to the supplier
  - to the Therapeutic Goods Administration
  - to NSW Poisons Information Centre (13 11 26) – if not already contacted regarding diagnosis and management.

## Further information

- Royal Children's Hospital Melbourne (2017), *Clinical Practice Guidelines: Anticholinergic Syndrome*. Access here.
- Paediatric Improvement Collaborative (2019), *Clinical Practice Guidelines: Unsettled or crying babies*. Access here.
- Therapeutic Guidelines (2020), *Anticholinergic alkaloid poisoning from plants*. Access via CIAP.
- Therapeutic Guidelines (2020), *Anticholinergic toxidrome*. Access via CIAP.