

# Medication Safety Notice

No. SA 07 / 24 page 1 of 2

Issued by the Office of the Chief Pharmacist, SA Health

[www.sahealth.sa.gov.au/medicationsafety](http://www.sahealth.sa.gov.au/medicationsafety)



A patient **Safety Notice** strongly advises the implementation of particular recommendations or solutions to improve quality and safety.

## We recommend you inform:

- General Managers
- Pharmacy Directors
- Medical Directors
- Clinical Directors
- Nursing Directors
- Drug and Therapeutics Committees
- Medication Safety Committees
- Safety and Quality Units
- Clinical Governance

## Contact details:

T: (08) 8204 1944  
E: HealthMedicationSafety@sa.gov.au

## Risk of toxicity from 'colic preparations' containing belladonna

### Background

There have been recent reports in other Australian states of calls to Poison Centres or of neonates/infants presenting to GPs or hospital emergency departments with suspected anticholinergic syndrome, after administration of a 'colic preparation' purchased online that contains belladonna. Advice from the Women's and Children's Hospital and from the Poison Information Centre indicate that there are currently no cases reported in South Australia. However, it is noted that patients may present to other health care settings for follow up.

This Medication Safety Notice is to inform SA 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.

### Belladonna toxicity

Belladonna is a plant that contains compounds that produce anticholinergic activity. Due to its anticholinergic properties, it is sometimes used as a base 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.

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.

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.

**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'.

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## Recommendations

1. 'Colic preparations' containing belladonna are **not recommended** to be given to neonates or infants.
2. 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.
3. Exercise heightened awareness of the possibility of belladonna toxicity following ingestion of 'colic preparations'. Ensure specific information regarding the formulation of 'colic preparation' is obtained during the history taking.
4. If anticholinergic syndrome is suspected, seek senior guidance and contact the 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.
5. Report any cases of suspected belladonna toxicity associated with 'colic preparations':
  - Via the Safety Learning System
  - To the supplier
  - To the [Therapeutic Goods Administration](#)
  - To the [Poisons Information Centre](#) (13 11 26)

## Ongoing action required by all LHNs and health services

1. Ensure that all relevant clinical, committees, hospital and clinical services staff are aware of this notice.

## Further enquiries

Further information including Clinical Practice Guidelines can be found [here](#) and additional information on anticholinergic syndrome can be found [here](#).

For any other enquiries or concerns, please contact your service pharmacist or pharmacy department directly; or email [HealthMedicationSafety@sa.gov.au](mailto:HealthMedicationSafety@sa.gov.au)