# Cough and cold remedies for children

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## Summary

**Over-the-counter cough and cold remedies for children under two years of age have recently been rescheduled to prescription-only. This will mean that doctors and pharmacists will encounter more consultations for such medicines. These drugs are no longer recommended in children because of the lack of efficacy and reports of serious adverse events.**

Key words: children, over-the-counter medicines.

*(Aust Prescr 2009;32:122–4)*

## Introduction

Upper respiratory tract infections are common in children and it is not surprising that cough and cold symptoms can be a major burden to many families. Until recently, over-the-counter (OTC) cough and cold remedies were widely available in Australia, and extensively used in young children. They include antitussives, antihistamines, expectorants and decongestants (Table 1). However, since September 2008 cough and cold medicines for children under two years have been rescheduled to S4 to become prescription-only. The USA and the UK introduced similar restrictions in response to reports of adverse effects, accidental overdoses and lack of evidence of their efficacy for acute and chronic cough in children.

This change in the scheduling of these medicines will result in more consultations, and doctors and pharmacists should be aware of the potentially serious adverse effects of these medicines. It is important to have a sound approach to providing symptomatic relief to children with cough and colds.

## Cough in children

Cough is a reflex response to mechanical, inflammatory and chemical irritation of the tracheobronchial tree. It is a normal mechanism for the maintenance of a healthy respiratory system.

### *Diagnosis*

When a child presents with cough or cold symptoms, the most important first step is to make the correct diagnosis and exclude serious pathology. Most causes of cough are self-limiting and do not require investigations. A detailed history and physical examination are most important, followed by specific investigations only when clinically indicated.

### *Causes of cough*

Management of a cough should be directed at the underlying cause. Cough that is accompanied by other upper respiratory tract infection symptoms, such as rhinorrhoea and sore throat, is usually due to viral infections and is rarely bacterial. If such a cough lingers, it may be a postinfective cough. A barking or brassy cough may suggest croup or tracheomalacia. Cough accompanied by respiratory distress suggests pneumonia or bronchiolitis. Asthma may present as nocturnal cough, while cough that disappears when the child is asleep may suggest a psychogenic cause.

A coughing infant or child with paroxysms of cough may have pertussis. Suppurative lung disease should be considered if the cough is most vigorous in the morning. If there is a temporal association with feeding or with positioning, gastro-oesophageal reflux should be considered.

The presence of a foreign body should be suspected after an acute episode of choking, while aspiration may occur in children with hypotonia or pharyngeal incoordination. Chlamydia trachomatis is an uncommon but serious cause of cough that should be considered especially if the infant has conjunctivitis or whose mother has evidence of chlamydial infection. Structural anomalies causing cough are usually associated with other symptoms such as stridor or cyanosis.

## Symptomatic treatments for colds and cough

Cough and cold symptoms can cause significant distress to children and their families, and this is reflected in the vast array of OTC medications marketed over the years. Most cough and cold remedies are a combination of antitussives, antihistamines, expectorants and decongestants. Table 1 lists their reported actions, common adverse effects and more serious adverse reactions.

### *Efficacy in children under two years*

Data on the efficacy of cough and cold medicines in children under two years old are extremely limited. There is no reliable evidence to recommend their use in this age group.

*Table 1*

**Common cough and cold remedies ***

| Drug type | Reported actions | Common adverse effects | Serious adverse reactions |
|---|---|---|---|
| **Antitussives** | | | |
| Pholcodine | Centrally acting opioid derivative; directly suppresses medullary cough centre | Dizziness, sedation, nausea | Opioid dependence, potential abuse, serotonin syndrome, lethargy, stupor, aspiration |
| Dextromethorphan | Narcotic analogue; directly suppresses medullary cough centre | | |
| **Antihistamines** Diphenhydramine Brompheniramine Chlorpheniramine | Histamine $H_1$-receptor antagonists; prevent histamine-induced reactions in cells of the respiratory tract, gastrointestinal tract and blood vessels | Sedation, headache, dizziness, nervousness, restlessness, irritability, palpitations | Hallucinations, seizures, central nervous system depression, cardiovascular collapse, apnoea, death, anticholinergic effects |
| **Decongestants** Pseudoephedrine Phenylephrine | Sympathomimetic drugs, adrenergic receptor agonists; produce vasoconstriction within the respiratory tract mucosa, and cause increased heart rate and cardiac contractility | Nervousness, restlessness, insomnia, trembling, headache, anxiety | Tachycardia, palpitations, dysrhythmias, hypertension, hallucinations, agitation, central nervous system depression, seizures |
| **Expectorants** Guaifenesin Ipecacuanha | Expectorants; promote the expulsion of mucus and other materials from the respiratory tract | Drowsiness, dizziness, headache, rash – these rarely occur at therapeutic doses | Nausea/vomiting, abdominal pain, nephrolithiasis |
| **Mucolytics** Bromhexine | Oral mucolytics; loosen and thin bronchial secretions by reducing surface tension and viscosity of mucus | Dizziness, headache, rash – these rarely occur at therapeutic doses | Nausea/vomiting, abdominal pain, diarrhoea |

* information modified from references 14 and 15

Note: these drugs are commonly sold as combination products

### *Efficacy in children over two years*

There have been numerous trials of cough and cold drugs in older children. A Cochrane review in 2008 found that treatments were no more effective than placebo for acute cough in children. The review included two trials with antitussives, two with antihistamines, two with antihistamine-decongestants and one trial with antitussive/bronchodilator combinations. One trial favoured active treatment with mucolytics over placebo.[1]

Another Cochrane review of three randomised controlled trials found that antihistamines had uncertain efficacy for prolonged non-specific cough (more than four weeks) in children compared to placebo.[2] The two larger trials showed no significant difference in symptom improvement. The smaller study indicated that cetirizine, a second generation antihistamine, was significantly more efficacious than placebo in reducing chronic cough in children with seasonal allergic rhinitis.[2]

In another Cochrane review, there was insufficient evidence to determine whether OTC medicines were beneficial for cough when given as an adjunct to antibiotics for acute pneumonia in children and adults.[3] Similar results were found in a review of nasal decongestants for the common cold in children.[4]

### *Non-drug treatments*

There are limited data on the use of non-pharmacological therapies for cough and colds. Nasal saline drops are effective in chronic rhinosinusitis[5], but there is limited evidence on their efficacy in the common cold. Steam and vapour are not recommended due to lack of efficacy data and the potentially serious adverse effect of burns. There is no evidence to show that physiotherapy is effective for cough other than when secondary to suppurative lung diseases. Cochrane reviews do not support the use of complementary medicines such as echinacea, vitamin C or zinc in the treatment of cough and colds.[6] A randomised controlled trial showed that honey was effective in children with cough[7], however there were many limitations to this study. In addition, ingestion of honey has been associated with infantile botulism and should not be used in children under one year.

## Why not prescribe cough and cold medicines?

Although the majority of trials analysed in the Cochrane reviews did not report adverse events, it is well known that cough and cold products in children are a major cause of unintentional

drug overdoses[8], and are associated with sudden infant deaths.[9] A recent report estimated that 7091 children under 12 years of age have been treated for adverse drug events in 63 emergency departments in the USA over two years.[10] Adverse reactions to drugs contained in cough and cold medicines have also been reported in Australia (www.tga.gov.au/ndpsc/record/rr200706.pdf).

The potential for adverse effects is high, firstly because until recently there was no regulation for dosing of such drugs in young children, and secondly because these medicines are often administered by multiple caregivers. In October 2008, the US Food and Drug Administration advised against the use of OTC cough and cold products in infants and children under two years of age, and recommended caution in children aged 2–11 years due to the risk of potentially life-threatening adverse effects.[11] These were described in the context of overdose or the use of multiple similar preparations. The Therapeutic Goods Administration made the same announcements in April 2008.[12] A recent recommendation in the UK advises that cough and cold medicines should not be used in children under six years.[13]

## Recommendations for managing coughs and colds

After excluding or treating the more serious underlying causes of cough, parents should be offered non-pharmacological advice on symptomatic treatment of coughs and colds. The first step is to explain the aetiology of symptoms and the mechanism of cough, and provide realistic information on the expected time-course of symptoms. Reassure parents that symptoms usually improve spontaneously and they have the option of continuing medical reviews.

Children with upper respiratory tract symptoms may benefit from adequate hydration and rest, together with symptomatic relief with analgesia, if required. If requests are made for the prescription of cold and cough remedies, parents should be given adequate information on the lack of evidence for their efficacy and the potential for significant adverse effects. Parents should also understand that such remedies will not change the course of their child's illness.

Cough and cold medicines must be avoided in children under two years and should not be recommended in children of any age, particularly those with neurological disorders, seizures, hypotonia, heart disease and those at risk of respiratory depression. Doctors and pharmacists should work together to avoid recommending the use of cough and cold remedies for children.

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## Further reading


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*Conflict of interest: none declared*