



# OVER-THE-COUNTER

## MEDICATION IN CHILDREN: FRIEND OR FOE?

**Cranswick N, McGillivray G. Over-the-counter medication in children: friend or foe? Aust Prescr 2001;24:149-51. Reprinted with permission from Australian Prescriber.**

### SYNOPSIS

Over-the-counter medications are often taken by adults, and given to children, to relieve minor ailments. Despite being freely available from a pharmacy or supermarket, many preparations are of unproven benefit. Some have the potential for harm, especially in the young. Health professionals, as well as parents, have a responsibility to be cautious about giving drugs to children.

### INTRODUCTION

The use of over-the-counter (OTC) medications has become commonplace in Australia. Not only do we, as adults, frequently medicate ourselves with OTC preparations, we give them to our children. The health professions and the community at large often assume that, because these drugs are not regulated by prescription, they are safe, even in overdose. However, the truth may be somewhat more sinister. While some are harmless placebos, others may be causing much more harm than good. Even the ubiquitous paracetamol may slow the body's response to viral infections and, in overdose, it can result in liver failure. Health professionals need to know about the efficacy and safety of OTC preparations in as much detail as they do about prescription medications. All too often, practitioners will recommend a preparation without sufficient knowledge of its potentially serious adverse effects or the evidence (or lack of) for its use.

### MEDICINES IN CHILDREN

There are fundamental differences between children and adults. Previous generations have treated children as small adults, often with dire consequences.<sup>1</sup> Drug regulatory history is littered with therapeutic misadventure involving children.<sup>2</sup> Nowhere is this plainer than in the story of Reye's syndrome and its association with aspirin, previously thought to be a useful and safe OTC medication for children.

**Sugar-free preparations:** Much is made of the importance of sugar-free preparations in the marketing of medicines for children. There is a general concern in the community about the effects of sugars upon children's behaviour. However, the only objective harmful effects of sugar are related to the development of dental caries and childhood obesity. Some preparations contain excipients which can be harmful to children with inborn errors of metabolism, e.g. phenylketonuria (PKU).

## DECONGESTANTS

There is little evidence for the use of either local or systemic decongestants in the symptomatic relief of viral infections. However, they are widely promoted for relieving the symptoms of cold and influenza.

**Oral decongestants:** A large number of OTC preparations include decongestants. These may be helpful for symptomatic relief of the symptoms associated with viral illnesses. However, prescribers should be aware that many preparations have age restrictions and some are contraindicated in children less than two years old. Often this group of medications is given by parents for their sedative properties. Occasionally, however, children react paradoxically with hyperactivity. Parents should be warned that this effect may last several hours and that further attempts at chemical restraint may only prolong the reaction. **Promethazine** is worthy of special mention. Although it is sedating and is used as a remedy for many ailments in children, it can cause paradoxical reactions with hyperactivity in toddlers. Children with epilepsy should use promethazine with caution as it may precipitate seizures. The product information also specifically warns against giving the drug to children under two years old, as its use has been linked to sudden infant death syndrome.<sup>3</sup>

**Nasal decongestants:** Topical nasal vasoconstrictors have been recommended in the past for babies and children with nasal congestion. In the short term, they will result in the clearing of the nasal passages. Unfortunately, tachyphylaxis may occur after a few days of regular use, and rebound nasal congestion can occur after cessation of the medication. In general, these formulations should be avoided. Intranasal saline solution is a safer alternative (for example 0.5 ml per nostril, one nostril at a time), however, it should be prewarmed to room temperature (for example in the parent's hands) in case the infant has a particularly sensitive diving reflex leading to bradycardia.

## ANTITUSSIVES

Cough is a common symptom in childhood and is usually related to viral bronchitis and upper respiratory infections.

These conditions are self-limiting and the cough probably serves a useful function in clearing mucus and preventing secondary infection. If a cough is particularly troublesome, other diagnoses should be considered before using an antitussive. Most cough medicines contain a mucolytic, antitussive, decongestant or some combination of these. The only proven antitussives are those containing opioids such as dextromethorphan and codeine. These work by suppressing the cough reflex centrally. Paediatricians do not recommend the routine use of these drugs. Overdose can cause drowsiness.

## ANALGESICS AND ANTIPYRETICS

**Paracetamol:** Paracetamol is often overused in the treatment of childhood fever<sup>4</sup> and there is a danger of liver toxicity.<sup>5</sup> In spite of these concerns, it should still be considered as first-line treatment for analgesia in children.

**Aspirin:** Aspirin is contraindicated in children less than 12 years old. Although it is a well-documented analgesic, anti-inflammatory and antipyretic, it has a strong association with Reye's syndrome. Now that the use of aspirin in children has all but ceased, Reye's syndrome has disappeared.<sup>6</sup>

**Ibuprofen:** Ibuprofen is a non-steroidal anti-inflammatory drug which has recently been marketed as an OTC preparation for children. Its efficacy is probably similar to that of paracetamol and it is currently used as an alternative to paracetamol for the management of pain and fever. While the drugs have similar safety profiles, ibuprofen is associated with a slightly increased risk of gastrointestinal bleeding, even at the low doses used in OTC formulations.<sup>7</sup> There have also been reports of renal toxicity and aspirin-like sensitivity reactions. There is limited experience with this drug in Australia.

## TEETHING GELS

An assortment of gels are commonly recommended for relieving the pain and discomfort of teething. While there are complications associated with teething, including drooling, teething gels have failed to demonstrate any specific benefit. It may be that the observed therapeutic effect is related to the actual gum massage. The gels commonly contain salicylic acid, lignocaine, tannic acid, menthol, thymol, glycerol and up to 40% ethanol. Some of these substances have the potential to be harmful in overdose, however teething gels are safe if used as recommended.

## TOPICAL APPLICATIONS

Topical moisturising creams and ointments are among the commonest preparations used by parents on their children. However, they are often not considered 'medications' and may not be reported to their physician. Fortunately, most of these products are emollients which can be safely applied to the face and body, and systemic absorption is minimal. They are particularly useful for dry skin and for atopic eczema. In general, ointments are best for dry skin while creams are used for moist lesions. For atopic eczema, aqueous creams should be applied at least three times a day to all the affected skin. The creams can be used with steroid-containing ointments. They can be used as alternatives to soap for washing, and should also be applied within three minutes of finishing a bath, to the whole body, and face. For very dry lesions, ointments may be more appropriate for trapping moisture in the skin. This can be achieved by adding 10% olive oil or 10% liquid paraffin to the aqueous cream. In severe eczema, especially if it wakes the child or if there is persistent redness or itching, wet dressings may be appropriate. An alternative is the application of a mixture of 50% liquid paraffin and 50% white soft paraffin (made up by the pharmacist). Adverse effects are uncommon, but some children experience stinging, and blocked pores or pimples and may require temporary discontinuation of the treatment.

**Topical steroids:** Most of the useful topical steroids are prescription medicines. However, low-potency preparations containing 0.5% hydrocortisone are available OTC. These preparations can be a useful adjunct to moisturisers in cases of mild eczema. Before recommending hydrocortisone a specific diagnosis should be made, and conditions exacerbated by steroids, such as fungal infections, should be excluded. Parents should be advised to seek early review if the treated skin condition fails to respond or worsens.

**Antifungal drugs:** Infants and children are prone to a range of fungal infestations. Oral infection or secondary infection of nappy rash by *Candida albicans* is common. Topical antifungal drugs such as nystatin or miconazole cream are effective, but need to be continued for a few days after clinical resolution. Ringworm can occur anywhere on the body and is caused by a range of dermatophytes. The diagnosis can be confirmed by microscopy and culture of skin scrapings. Most cases in children can be treated with topical antifungals such as miconazole. Terbinafine cream is very effective in adults, but is not currently recommended for use in children. Resistant cases, or those involving the scalp or nails, may require systemic therapy.

## REHYDRATING FLUIDS

One of the great advances in the treatment of gastroenteritis has been the recognition that appropriate oral rehydration is the best form of therapy. Balanced electrolyte solutions can easily be prepared by parents, but the instructions should be carefully followed as over-concentrated solutions can cause osmotic diarrhoea. Compliance may be enhanced by the use of one of the flavoured solutions and by pre-chilling the drink.

## ANTICOLIC PREPARATIONS

Persistent crying, or 'colic' is common in the first three months. Any suspicions of underlying organic disease, especially of the gastrointestinal (failure to thrive) or urinary tract (fever), should be investigated and excluded before making the diagnosis of colic. Colic has not been proved to be due to 'wind' or 'gas' and may well be a normal developmental phase for many infants. The currently available products contain either simethicone (an anti-gas agent) or a combination of anticholinergics, but none of these has been shown to be effective. In the majority of cases, clinical exclusion of serious pathology and parental reassurance and support is all that is required. However, in severe cases, parental distress exceeds the infant's distress and an effective treatment regimen may include either in-patient or outpatient attendance at a mother/baby unit

## TREATMENTS FOR REFLUX

Many infants vomit, this is usually associated with a poorly or incompletely developed lower oesophageal sphincter. In most cases, this is mild and resolves spontaneously with age. In mild cases, posturing and thickened feeds with one of the many available anti-reflux infant feeding formulae may provide symptomatic relief. Severe or persistent cases should be investigated particularly if there is weight loss or failure to thrive.

## COMPLEMENTARY AND ALTERNATIVE MEDICINES

Complementary medicines such as echinacea and aloe vera are not OTC medicines and are not registered as such. Specific product information is not generally available. Currently in Australia, there is a listing system for these products. This ensures that the manufacturing process complies with certain standards, but no review of efficacy or safety in children is included. Medical practitioners and pharmacists should be aware of the widespread use of complementary medicines.

## SOURCES OF INFORMATION\*

There are few reliable sources of information on OTC preparations. Practitioners should initially consult the product information<sup>8</sup> and dosing information for many of the medications is available.<sup>8,9,10,11</sup> A few indications covered by the reviews of the Cochrane Collaboration are nasal decongestants for the common cold,<sup>12</sup> topical antifungals<sup>13</sup> for skin infections and vitamin C for the common cold.<sup>14</sup> In cases of overdose, the local poisons information centre should be consulted.

## CONCLUSION

OTC medications are commonly used for the temporary relief of minor ailments in children. Some, such as topical moisturisers and oral rehydration fluids, have a real place in therapy. Many, such as the nasal decongestants, are of little use and may have unwanted adverse effects. Others, such as aspirin, are contraindicated in children. Practitioners should question parents about all the therapies that they are giving their children. They should also consult appropriate references before recommending OTC medicines for children.

## ACKNOWLEDGEMENT

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**\*In New Zealand the following sources can be used for information on OTC medicines:**

- MIMS New Ethicals. January 2007 Edition. Auckland. CMP Medica (NZ) Ltd. 2007.
- Medicine Data Sheets. Wellington. Medsafe. Ministry of Health.  
Available from <http://www.medsafe.govt.nz/profs/Datasheet/dsform.asp>

## REFERENCES

1. Yaffe SJ, Aranda JV. Introduction and Historical Perspectives. In: Yaffe SJ, Aranda JV, editors. Pediatric pharmacology, Therapeutic principles in practice. Philadelphia: W.B. Saunders Co.; 1980. p. 3-9.
2. Wilson JT. Strategies for pediatric drug evaluation: a view from the trenches. Drug Inf J 1996;30:1149-62.
3. Stanton AN. Sudden infant death syndrome and phenothiazines. Pediatrics 1983;71:986-8.
4. Hewson P. Paracetamol: overused in childhood fever. Aust Prescr 2000;23:60-1.
5. Shann F. Paracetamol: use in children. Aust Prescr 1995;18:33-5.
6. Belay ED, Bresee JS, Holman RC, Khan AS, Shahriari A, Schonberger LB. Reye's syndrome in the United States from 1981 through 1997. N Engl J Med 1999;340:1377-82.
7. Lesko SM, Mitchell AA. An assessment of the safety of pediatric ibuprofen. A practitioner-based randomized clinical trial. JAMA 1995;273:929-33.
8. 2000 MIMS OTC. 3rd ed. Sydney: Havas MediMedia Australia Pty Ltd.;2000.
9. Paediatric Pharmacopoeia. 12th ed. Melbourne: Pharmacy Department, Royal Children's Hospital; 1998.
10. Australian Medicines Handbook. 2nd ed. Adelaide: Australian Medicines Handbook Pty Ltd.; 2000.
11. Sansom L, editor. Australian Pharmaceutical Formulary and Handbook. Canberra: Pharmaceutical Society of Australia; 2000.
12. Taverner D, Bickford L, Draper M. Nasal decongestants for the common cold (Cochrane Review). In: The Cochrane Library, 3, 2001. Oxford: Update Software.
13. Crawford F, Hart R, Bell-Syer S, Torgerson D, Young P, Russell I. Topical treatments for fungal infections of the skin and nails of the foot (Cochrane Review). In: The Cochrane Library, 3, 2001. Oxford: Update Software.
14. Douglas RM, Chalker EB, Treacy B. Vitamin C for preventing and treating the common cold (Cochrane Review). In: The Cochrane Library, 3, 2001. Oxford: Update Software.