

Information factsheet

Current Restrictions on Children's OTC Cough and Cold Medicines

Restrictions on the sale of cough and cold medicines for use in children were introduced in stages by the Medicines and Healthcare Products Regulatory Agency (MHRA), as growing evidence demonstrated a lack of efficacy and safety of specific ingredients used in such preparations.

- **March 2008** – Initial restrictions introduced - applicable to children aged 2 years of age and under.
- **February 2009** – The age limit was further extended to include all children aged 6 years and under. Additionally, certain restrictions were also applied for children aged between 6 to 12 years.
- **October 2010** – Sale of codeine-containing liquid cough preparations restricted – not to be used in children under 18 year old.

Which active ingredients are affected by the restrictions?

- Brompheniramine
- Codeine
- Chlorphenamine
- Dextromethorphan
- Diphenhydramine
- Doxylamine
- Ephedrine
- Guaifenesin
- Ipecacuanha
- Oxymetazoline
- Phenylephrine
- Pholcodine
- Promethazine
- Pseudoephedrine
- Tripolidine
- Xylometazoline

Children under 6 years old

OTC medicines containing one or more of the restricted ingredients (see above) **and** licensed for the relief of cough and cold symptoms must **NOT** be sold for use in children under 6 years old.

The following **symptomatic treatment**, if required, can be recommended for a child aged under 6 years:

- Ibuprofen or paracetamol, to relieve fever and/or pain
- Simple cough mixtures containing glycerol, honey and lemon, or simple linctus
- Vapour rubs, inhalants and saline drops, to treat nasal congestion.

Non-pharmacological interventions such as raising the head of the bed, tickling the nose with a cotton bud to induce sneezing prior to a feed for babies, getting plenty of rest and increasing fluid intake can also be recommended.

Children between 6 and 12 years of age

First-line treatment of cough and colds in children of this age group should be according to the symptomatic treatment and non-pharmacological interventions listed in the box above. As second-line options, cough and cold remedies containing any of the restricted active ingredients (except codeine) may continue to be sold through pharmacies for a **maximum treatment period of five days only**.

Current Restrictions on OTC Cough and Cold Medicines in Children

Pharmacists are advised to check the licensing of each individual product before recommending a suitable preparation as it may not be indicated for children in this age group; for example, Robitussin Chesty Cough Medicine (active ingredient guaifenesin) is now only licensed for use in children over 12 years of age.

Children and young people between 12 and 18 years of age

There are no restrictions in place for this age group with the exception of OTC liquid medicines containing codeine for symptomatic treatment of cough, which should not be sold for children and young people under 18 years of age. See below for a detailed explanation on the restrictions for sale of codeine.

Restrictions on OTC sales of codeine containing linctus for children less than 18 years

Introduced in October 2010, codeine containing linctus should **NOT** be sold to children and young people under 18 years of age for the treatment of cough. The evidence suggests that the associated risks of OTC medicines for children containing codeine outweigh the possible benefits.

Additionally:

- All OTC liquid medicines containing codeine should be packaged in Child Resistant Containers (CRCs) by June 2012.
- The SPC, PIL and packaging of all codeine containing medicines should carry a breast-feeding warning as there is a risk of side effects in breast fed babies from maternal use of codeine.
- Pharmacists are asked to consider this new advice if supplying any codeine containing product to breastfeeding mothers.

Exclusion to the restrictions

Please be aware that this restriction does not affect products which are **NOT** licensed for relief of cough and cold symptoms and therefore would not apply to a product such as Piriton (containing chlorphenamine as an active ingredient) which is licensed for treating allergic conditions.

Further information

NPA Information Department:

Telephone 01727 891800/0844 7364201 or email: information@npa.co.uk

MHRA:

<http://www.mhra.gov.uk/NewsCentre/Pressreleases/CON038902>

<http://www.mhra.gov.uk/NewsCentre/CON028268>