



Children's over-the-counter cough and cold medicines: New advice

Fonte: MHRA

<http://www.mhra.gov.uk/Safetyinformation/Safetywarningsalertsandrecalls/Safetywarningsandmessagesformedicines/CON038908>

Over-the-counter (OTC) cough and cold medicines for children have been under review in the UK.

The Commission on Human Medicines (CHM) has advised on a package of measures to improve safe use of cough and cold medicines for children under 12.

The new advice is that parents and carers should no longer use over-the-counter (OTC) cough and cold medicines in children under 6. There is no evidence that they work and can cause side effects, such as allergic reactions, effects on sleep or hallucinations.

For 6 to 12 year olds these medicines will continue to be available but will only be sold in pharmacies, with clearer advice on the packaging and from the pharmacist. This is because the risks of side effects is reduced in older children because they weigh more, get fewer colds and can say if the medicine is doing any good. More research is being done by industry on how well these medicines work in children aged 6-12 years.

Manufacturers are currently updating the packaging and leaflets for cough and cold products authorised for use in children aged over 6 years to include the updated advice. Products with the new information will begin to appear later in 2009, and in the meantime existing medicines will continue to be sold as before.

Cough and cold medicines should be administered carefully in accordance with the manufacturer's instructions to ensure the child does not receive more than the maximum dose.

The safety of all medicines is continually reviewed by the MHRA and action taken as necessary to minimise risk if new safety hazards are identified

The advice for parents/carers is that they should follow advice to relieve symptoms as outlined in the [Department of Health's 2007 guidance 'Birth to Five'](#). (external link)

Advice for parents/carers

What should I do with the products I have in my cupboard?

You should review these to see whether there are any which you no longer need or are no longer suitable for under 6s.

Do I need to worry if I have just given one of these medicines to my child?

Provided that the child has been given the dose as recommended on the bottle, you do not need to worry; but if you have concerns about the condition of your child, you should contact a health professional - for example, by calling NHS Direct **0845 46 47**. You should review the medicines which you have, to see whether there are any which you no longer need; these can be taken to any pharmacy for disposal.

So what should we do when a child has a cough/cold?

Cough and colds are self limiting conditions and will usually get better by themselves. Simple measures such as ensuring your child has plenty to drink and gets enough rest will help. Paracetamol or ibuprofen can also be used to reduce your child's temperature. For young babies, particularly those who are having difficulty feeding, nasal saline drops are available to help thin and clear nasal secretions. If your child is








over the age of one, a warm drink of lemon and honey may help to ease a cough. If your child is not getting better after 5 days, ask a healthcare professional for advice.

Can I still give my child ibuprofen or paracetamol?

You can give your child ibuprofen or paracetamol, in accordance with the instructions on the label, provided the child is not taking any other medicine which contains these ingredients.

Per approfondimenti:

-  1. Press release: Better medicines for children's coughs and colds (52Kb):
http://www.mhra.gov.uk/home/idcplg?IdcService=GET_FILE&dDocName=CON038903&RevisionSelectionMethod=LatestReleased
-  2. Healthcare professional letter: Over-the-counter cough and cold medicines for children (120Kb):
http://www.mhra.gov.uk/home/idcplg?IdcService=GET_FILE&dDocName=CON038904&RevisionSelectionMethod=LatestReleased
-  4. Questions and answers: Over-the-counter cough and cold medicines for children (16Kb):
http://www.mhra.gov.uk/home/idcplg?IdcService=GET_FILE&dDocName=CON038905&RevisionSelectionMethod=LatestReleased
-  3. Lists of products that are affected by the new advice on over-the-counter cough and cold medicines for children - updated on 16 April 2009 (550Kb):
http://www.mhra.gov.uk/home/idcplg?IdcService=GET_FILE&dDocName=CON038907&RevisionSelectionMethod=LatestReleased
-  5. Overview - Risk: benefit of over-the-counter (OTC) cough and cold medicines (66Kb):
http://www.mhra.gov.uk/home/idcplg?IdcService=GET_FILE&dDocName=CON041374&RevisionSelectionMethod=LatestReleased