



## IRISH MEDICINES BOARD

Monday 19 September, 2011

### **IMB GIVES NEW ADVICE FOR USE OF COUGH AND COLD MEDICINES IN CHILDREN**

The Irish Medicines Board (IMB) states today that it is recommending a number of new measures in relation to the use of over the counter (OTC) cough and cold medicines for children. Following a review by the IMB of the safety and effectiveness of these medicines, it is advising that OTC cough and cold medicines are no longer used in children **under the age of six years**. New product information for these medicines is currently in the process of being updated to reflect this advice.

The IMB states that people who have used these products in the past should not be concerned. Its review found no robust evidence that these medicines work effectively in children under six, however, there have been some reports of side effects such as allergic reactions and drowsiness associated with their use. Given there are few benefits for children under six years in taking these medicines but there are some risks, the IMB is recommending that they should no longer be used.

For 6 to 12 year olds, the IMB is advising that these medicines can continue to be used but care should be taken to ensure that the maximum daily dose is not exceeded and that no other cough or cold medicine is taken at the same time.

According to Dr Joan Gilvarry, Director of Human Medicines, IMB, coughs and colds occur frequently in children, especially in younger children but they generally resolve within a number of days.

“Using simple measures such as plenty of fluids and rest to ease the symptoms are likely to be effective, but paracetamol and ibuprofen can be used to assist in reducing the temperature if needed. If your child is not getting better or you have any concerns about their condition you should consult with your doctor or pharmacist. In children over the age of six years, these cough and cold medicines can continue to be used where necessary. This is because the risk of side effects is reduced in older children as they weigh more, get fewer coughs and colds and can say if the medicine is working or not.”

#### **Key Recommendations:**

1. Cough and cold medicines containing certain active ingredients\*\* **should not be used in children under six years** as the benefit-risk balance in this age group has not been shown to be favourable.
2. For children aged 6 to 12 years, OTC medicines to treat cough and colds can continue to be considered where necessary. Care should be taken to ensure adherence to the maximum daily dose and to ensure that the product is not taken with another cough and cold medicines.
3. In the context of paediatric use, OTC cough and cold medicines containing the active ingredients listed below will continue to be available for use in children aged between 6 and 12 years, but in pharmacies only, where advice can be given regarding their use.

The product information for these medicines, including the package leaflet, is currently in the process of being updated to reflect this new advice. The introduction of OTC cough and cold medicines with the updated labelling has already commenced for the 2011 cough and cold season, and the products with updated labelling will continue to be introduced to pharmacies over the coming months.

A letter has also been sent to all General Practitioners and Pharmacists to advise them of these changes. This letter is available on the IMB website [www.imb.ie](http://www.imb.ie).

#### ENDS

#### FOR FURTHER INFORMATION:

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#### ABOUT THE IRISH MEDICINES BOARD

The Irish Medicines Board (IMB) is the competent authority for the licensing of human and veterinary medicines and medical devices in Ireland. Its role is to protect and enhance public and animal health through the regulation of medicines, medical devices and healthcare products

#### CATEGORIES OF PRODUCTS AFFECTED

Cough and cold medicines available over the counter and containing the following ingredients are affected by the new recommendations.

The affected products contain one or more of the active ingredients listed in the chart below. They fall into four broad categories: antihistamines, antitussives, expectorants and decongestants.

Category of medicine (Purpose)	**Active Ingredients
Antihistamines in cough and cold medicines (used to treat sneezing, runny nose)	brompheniramine diphenhydramine doxylamine triprolidine
Antitussives (used to treat cough)	dextromethorphan pholcodine
Expectorants (used to loosen mucus)	Guaifenesin Ipecacuanha
Decongestants (used to treat congestion)	phenylephrine pseudoephedrine oxymetazoline xylometazoline

**The names of the products which contain these ingredients are as follows:**

Actifed Syrup  
Benylin Four flu oral solution  
Benylin Four flu tablets  
Benylin Childrens Chesty Cough syrup  
Benylin Childrens Cough and Colds syrup  
Benylin Childrens Dry Coughs syrup  
Benylin Cough Medicine syrup  
Benylin Dry Coughs syrup  
Benylin Dual Action Chesty Cough syrup  
Benylin Dual Action Dry Syrup  
Benylin NonDrowsy for Chesty coughs syrup  
Benylin NonDrowsy for Dry coughs syrup  
Casacol Expectorant syrup  
Day Nurse capsules  
Ilvico tablets  
Lemsip Chesty Cough Oral Suspension  
Lemsip Cough and cold capsules with caffeine  
Lemsip decongestant and flu capsules with caffeine  
Nirolex Chesty cough and decongestant oral solution  
Nirolex Day Cold and Flu capsules  
Nirolex Dry coughs with decongestant oral solution  
Non-drowsy Sudafed decongestant syrup  
Otrivine Child Nasal drops  
Pholcodex oral solution  
Robitussin Chesty Cough oral solution  
Robitussin Dry Cough oral solution  
Robitussin Plus oral solution  
Non-drowsy Sinutab tablets  
Sudafed Nasal spray solution  
Tixylix Chesty Cough  
Venos Expectorant oral solution  
Venos honey and lemon oral solution