



IRISH MEDICINES BOARD

September 19th 2011.

Dear Healthcare Professional,

New Advice regarding Non-prescription cough and cold medicines for young children

The Irish Medicines Board (IMB) wishes to inform you of the outcome of its review of the safety and efficacy of Non-prescription Cough and Cold medicines authorised for use in children.

Key Recommendations include the following:

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. The list of these active ingredients is provided below.
2. For children aged 6-12 years, non-prescription medicines to treat coughs 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 a product is not taken with any other cough and cold medicine.
3. In the context of paediatric use, non-prescription 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.

Active ingredients affected:

Non-prescription cough and cold medicines containing the following active ingredients are affected by the new recommendations:

Antitussives: dextromethorphan and pholcodine*

Expectorants: guaifenesin and ipecacuanha

Nasal decongestants: oxymetazoline, phenylephrine, pseudoephedrine and xylometazoline

Antihistamines: brompheniramine, diphenhydramine, doxylamine and triprolidine

Rationale and background to the recommendations

These recommendations reflect an evolution in the therapeutic strategy over time for the management of coughs and colds in children rather than the emergence of any new safety concern.

It is recognised that coughs and colds occur frequently in children and are generally self-limiting.

As there is no robust evidence regarding the efficacy of cough and cold medicines containing the above ingredients and given that there have been some reports of harm globally with these

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ingredients, the risks of cough and cold medicines containing them are now considered to outweigh their benefits in children less than 6 years.

For children aged 6 years and over, the risk from these ingredients is reduced because they suffer from coughs and colds less frequently and consequently require these medicines less often; with increased age and size, they may tolerate these medicines better; and they can usually say if the medicine is working. Therefore, non-prescription cough and cold medicines containing the above ingredients can continue to be available for these older children aged 6 to 12 years, but through pharmacies only.

Implementation of updated product information

The IMB is working with manufacturers to implement these measures and the product information for these medicines is being updated to reflect the new advice. The introduction of non-prescription 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. At this time, it is considered that a recall or an immediate withdrawal of products with the older labelling is not necessary, because of their established use over many decades.

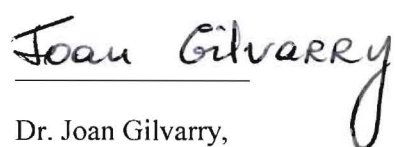
These medicines can still be used in children aged between 6 and 12 years and in adults. Since the labelling for some of these products may also include dosing information for adults and older children on the same label, it is recommended that during the forthcoming cough and cold season of 2011, any outstanding non-prescription cough and cold medicines with the old labelling may remain in place until the new labelling has been fully phased in.

It would be appreciated if the contents of this letter on the updated recommendations for use of paediatric non-prescription cough and cold medicines could be highlighted to other relevant staff, where appropriate.

The Summaries of Product Characteristics for the affected products have been updated to reflect the new recommendations and are available on www.imb.ie.

If you have any queries in relation to this letter please contact IMB by email: customerservice@imb.ie or by telephone: 01-6764971.

Yours sincerely,



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*Pholcodine containing products are currently subject to an EU review on the benefits and risks of these products. The outcome will be communicated once available. The above recommendations apply to pholcodine containing products in the interim pending any further changes.

Over the Counter (OTC) cough and cold products involved in the IMB review which are no longer recommended for use in children under 6 years.

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