



IRISH MEDICINES BOARD

12 March, 2012

New Dosage Instructions for Children's Liquid paracetamol medicines

Dear Healthcare Professional,

The Irish Medicines Board (IMB) wishes to inform you that new dosage instructions will be included on the product information supplied with liquid paracetamol medicines* for paediatric use.

IMB Recommendations:

The IMB has recommended that the following updates be made to the product information for liquid paracetamol medicines with a paediatric indication, in order to ensure that children get the most effective amount of paracetamol for their age and to optimise the safe use of these products:

1. *Paediatric posology for liquid oral formulations of paracetamol will be altered to a posology based on narrower age bands with a single dose per band. (Please see recommended dosage template below).*
2. *Liquid paracetamol medicines for paediatric use should be administered with a suitable measuring device to assist accurate administration.*

Active ingredients affected:

Single-constituent liquid paracetamol medicines for paediatric use.*

Rationale and background to the recommendations:

The IMB recommendations represent a refinement of the existing paediatric posology for liquid paracetamol products rather than a response to any safety concern.

Paediatric paracetamol dosage can be calculated in mgs per kg body weight for individual patients. However, this is not always practical for parents to manage at home. In the context of clarifying paracetamol posology for parents administering liquid paracetamol products, the new doses recommended by the IMB more closely match amounts based on body weight by introducing narrower age bands, and by defining a single dose per age band, which increases between age bands stepwise by 2.5 ml.

The overall aim is to ensure that children receive the optimal dose of paracetamol for their age.

The product information containing the new dosage instructions represents a proportionate move to further enhance the balance of benefits and risks for these medicines.

Bord Leigheasra na hÉireann

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Implementation of the updated dosage instructions:

The IMB has been working with Marketing Authorisation Holders to implement the new dosage instructions in the product information. Medicines with the new dosage information will begin to appear later this month or early April 2012 and will continue to be introduced to pharmacies and stores over the coming months.

It is not considered that a recall of medicines with the current dosage instructions is necessary at this time due to their established use over many decades.

The new dosage instructions will make it easier for parents and carers to know exactly how much paracetamol they should give their children. In the meantime, as this is not a safety issue, the IMB is advising parents and carers to follow the instructions on the current product information.

Details of the IMB dosing recommendations:

There are two different strengths of liquid paracetamol formulations for children and the changes apply to both.

The new dosing schedule includes narrower age bands and will define a single dose per age band.

Infant paracetamol suspension (120 mg/5mL)

Under the current dosage instructions, liquid paracetamol-containing medicines (**120mg/5mL**) have two single age bands ranging from 3 months to 1 year and from 1 year to 6 years.

In the updated instructions, there will be four separate age bands of 3-6 months, 6-24 months, 2-4 years and 4-6 years with one dose recommended for each age band as follows:

Child's Age	How Much	How often (in 24 hours)
3 – 6 months	2.5 mL	4 times in 24 hours
6 – 24 months	5 mL	4 times in 24 hours
2 – 4 years	7.5 mL	4 times in 24 hours
4 – 6 years	10 mL	4 times in 24 hours

Paracetamol six plus suspension (250 mg/5mL)

For liquid paracetamol-containing medicines for children aged over 6 years (250mg/5mL), the following new age bands and doses will apply:

Child's Age	How Much	How often (in 24 hours)
6 – 8 years	5 mL	4 times in 24 hours
8 – 10 years	7.5 mL	4 times in 24 hours
10 – 12 years	10 mL	4 times in 24 hours

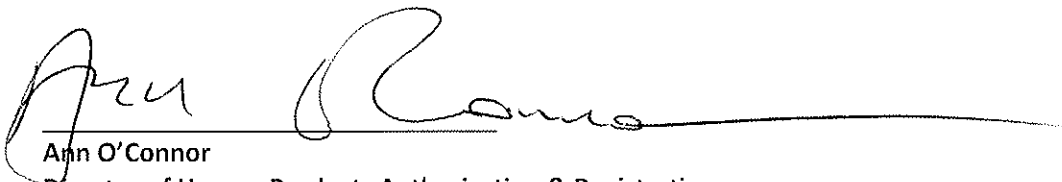
Parents should be reminded to carefully read the product information (package leaflet and label), to ensure that the dosing interval and the maximum daily dose recommended on the packaging are never exceeded and to ensure that no other paracetamol-containing medicine is administered.

The Summaries of Product Characteristics for the relevant medicines have been updated to reflect the new dosage instructions and are available on www.imb.ie.

It would be appreciated if the contents of this letter could be highlighted to relevant staff, where appropriate.

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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See list of affected medicines overleaf

***List of Medicines Affected**

- CALPOL 120mg/5ml Oral Suspension
- CALPOL 120 mg/5ml INFANT ORAL SUSPENSION. 120 Oral Suspension
- CALPOL SUGAR FREE INFANT 120mg/5ml Oral Suspension
- CALPOL SIX PLUS 250mg/5ml Oral Suspension
- CALPOL SIX PLUS 250mg/5ml Oral Suspension
- MEDINOL UNDER 6 PARACETAMOL ORAL SUSPENSION 120 mg/5ml Oral Suspension
- MEDINOL OVER 6 250mg/5ml Oral Suspension
- PANADOL BABY 120mg/5 mL, ORAL SUSPENSION
- PARACETAMOL INFANT 120mg/5ml Oral Suspension
- PARACETAMOL SUGAR FREE INFANT 120mg/5ml Oral Suspension
- PARALINK PARACETAMOL ORAL SOLUTION 120mg/5ml
- PARALINK SIX PLUS PARACETAMOL 250 mg/5 ml Oral Solution
- JUNIOR PARAPAED PARACETAMOL ORAL SUSPENSION 120 mg/5 ml
- SIX PLUS PARAPAED PARACETAMOL ORAL SUSPENSION 250 mg/5 ml